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EUROPEAN CHEMICALS AGENCY

Progressing together to identify substances of concern

Roadmap for SVHC identification and implementation of REACH risk management measures - Annual Report

April 2017

Roadmap for SVHC identification and implementation of REACH risk management measures

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List of abbreviations

Abbreviation	Description
ACT	Activities Coordination Tool
Art.	Article
CCH	Compliance check under dossier evaluation
CLH	Harmonised classification and labelling
CLP	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of December 2008 on classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, mutagenic, toxic for reproduction
CG	Coordination group
CoRAP	Community rolling action plan
COM	Commission
ECHA	European Chemicals Agency
ED	Endocrine disruptor
EG	Expert group
ELoC	Equivalent level of concern
MS	Member State
PBT	Persistent, bioaccumulative and toxic
(Q)SAR	(Quantitative) structure-activity relationship
PACT	Public Activities Coordination Tool
PETCO	Petroleum and coal streams
POP	Persistent organic pollutant
RAC	Committee for Risk Assessment
REACH	Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RIME	Risk Management Expert Meeting of Member State competent authorities
RIP	Roadmap implementation plan
RMOA	Risk management option analysis
SEv	Substance evaluation
STOT RE	Specific target organ toxicity – repeated exposure
SVHC	Substance of very high concern
vPvB	Very persistent and very bioaccumulative

Foreword

Welcome to this report on progress towards having all relevant substances of very high concern (SVHCs) on the Candidate List. It is the third such report where you can see details of progress and get an impression of the behind-the-scenes work that the Agency together with the Member States has been doing to identify the chemicals of most concern. It is also my last foreword, as my mandate as Executive Director of ECHA ends this year. For that reason, I want to take a step back and reflect on what we have achieved since the European Council adopted the SVHC Roadmap in February 2013.

First of all, let's not forget where we came from. Before REACH, hazardous chemicals consumed in Europe were regulated by around 40 pieces of legislation. Now, 10 years after the entry into force of REACH and four years after our collective agreement to ensure that the most hazardous substances are on the Candidate List, we have 173 SVHCs on the list, more than 200 substances with a harmonised classification, 20 new restrictions and over 500 substances of potential concern under further information generation and assessment. I'm proud of that progress – and I hope that you are too.

Of course, we probably all wish that the process was even speedier – that is why we have decided to work more on groups of substances and in collaboration with the relevant sectors – and that the policy makers have less hesitation in putting forward new risk management proposals or in approving the decisions related to SVHCs. Some companies will inevitably be negatively impacted by these decisions, but others will work on alternatives and reap the benefits. Predictable and stepwise phasing out of the substances of most concern stimulates innovation in new substances and alternative technologies.

I also need to mention the one fundamental stumbling block for everything we do to protect human health and the environment – that of the compliance of registrations with the REACH and CLP requirements. Put simply, if the data is insufficient for us to make an informed judgement about the risks of a chemical, then there are two significant consequences – we and the national authorities are wasting time chasing data on innocuous substances and, much worse, we may not be prioritising the substances that really are of most concern. This is not a new message. It's one that I have made on almost every occasion when I have spoken or written about our work. The compliance of the data provided by companies has got to improve. The best companies do this well – they take pride in providing reliable data to us and to their customers and they see it as an integral part of their business strategy towards a sustainable future. I am sure that the pressure on other companies to follow suit will only grow, but I for one am becoming impatient for this to happen, on behalf of the citizens, in whose name we do this work.

My sincere thanks go to all our colleagues in the Member States for their work with us in identifying and addressing substances of concern. I am very pleased to see that, over time, more Member States have become involved, which is to everyone's benefit.

Thank you for taking the time to have an interest in this report and I wish you – and my colleagues in ECHA and the Member States – the greatest of success in seeing this work through to its satisfactory conclusion: the effective risk management of the most hazardous substances in Europe. It's an important and worthwhile objective, and one that I have been proud to work towards over the last 10 years.

Geert Dancet

Executive Director

Executive summary

Early in 2013, the Member States, the European Commission and ECHA agreed a plan to have all relevant currently known substances of very high concern on the Candidate List by 2020. We are now half way to that goal. Work is progressing well and we continue to believe that the target will be met.

To have the maximum effect in the shortest possible time, it is important to prioritise substances where the impact on human health and the environment is highest, and to identify the most effective way of confirming and addressing the concerns. This objective is central to ECHA's Integrated Regulatory Strategy and is done collaboratively with the Member States – which is a key element of the success of this work. It is equally important that companies can see which substances are going to be examined and when – they can then more efficiently play their own role in providing information to enable us to make proper selections. This is achieved by listing the substances being looked at in the Public Activities Coordination Tool (PACT)

During the first three years of the roadmap implementation, ECHA and the Member States have already addressed all the substances for which there was sufficient information on the hazard properties. In some cases, the authorities have concluded that they do not need further risk management. In all other cases, they are in the regulatory risk management processes – being identified as SVHCs, being subject to authorisation, having their classification harmonised, being restricted, or undergoing an analysis of the risk management options. The main focus of the work from now on is identifying substances which could be of concern, but where more information is needed before concluding.

Each year, ECHA has screened the full REACH/CLP substance database to identify potential substances for further work. From this exercise, around 900 substances have been proposed to the Member States for further manual screening and in the last three years, **more than 600 of them have been scrutinised**. In 2016, 184 were manually screened and 72 % needed follow-up action. Usually more data is needed, which is requested either as a result of a dossier compliance check or a substance evaluation. This common manual screening has also brought the key actors together – 22 Member States contributed to the manual screening in 2016.

More than **500 substances are currently having new data generated or are having data assessed.** Almost half of them are having their dossiers' compliance checked and for around 85 % of them we need to clarify whether they have PBT, ED and/or CMR properties. In 2016, the data requested for substances in the Community rolling action plan (CoRAP) of 2012/2013 started to arrive, and more will come in 2017. This data will increasingly enable us to confirm or refute the concern identified through screening and to initiate regulatory risk management where needed.

Generating new data and concluding on hazardous properties takes time. However, experience shows that the final confirmation of the properties can be done swiftly - even for demanding PBT and ED cases. Integrating the different processes and bringing together the expertise of Member States and stakeholders has been essential to achieving this. Most substances listed on the CoRAP with potential PBT or ED properties are first discussed in the PBT or ED Expert Group to identify the best possible testing. All substances proposed for SVHC identification due to their PBT and/or ED properties have also been discussed in these expert groups allowing more efficient decision-making.

Due to the lack of information on the hazards of substances and on how they are used, it is more and more difficult to identify substances that warrant further scrutiny. Therefore, we move to working more with groups of structurally similar substances. This should speed up the process

because it should allow us to draw conclusions on a larger number of substances. But it also requires more cooperation and coordination between ECHA and the Member States. Working with groups of substances will increase consistency of the authorities' work. It also helps industry to avoid substituting substances of concern with substances that have similar properties.

The number of **RMOAs** either under development or concluded slightly increased in 2016, with 159 substances listed since 2013. Conclusions on 67 RMOAs have been published. Around half of those resulted in the conclusion that they be identified as substances of very high concern. Those RMOAs have all been followed by the submission of an Annex XV dossier.

Since 2013, 15 Member States and ECHA have been involved in producing RMOAs. In 2016, the number of new RMOAs was lower than in previous years (16 RMOAs). This was partly because for many cases further hazard information was needed. In addition, the new screening has reduced the need for them. It is worth noting that four of those RMOAs were developed for large groups of substances (e.g. sensitisers in textiles), thereby covering a much larger number of individual substances. Nevertheless, the overall number of RMOAs is substantially less than originally planned in the roadmap. This year ECHA, together with the Member States and the Commission, is reviewing how we implement the SVHC Roadmap, including the RMOA approach and its role.

1 Introduction

The Roadmap for SVHC identification and implementation of REACH risk management measures from now to 2020 (SVHC Roadmap) gives an EU-wide commitment for having all relevant currently known substances of very high concern (SVHCs) identified and included on the Candidate List by 2020.

Furthermore, it supports carrying out and further integrating other REACH and CLP processes with a view to starting further regulatory risk management where needed.

The roadmap endeavours to conclude on all substances, either that:

1. they are of concern and these identified concerns need to be addressed; or
2. they are of lower concern and do not require further regulatory attention at the moment.

Several activities may need to be combined starting from screening, data generation and assessment, RMOA to finally ending up (or not) in one of the REACH and CLP processes.

Therefore, the SVHC Roadmap implementation work should also provide a strong basis for the work beyond 2020 to identify the substances which matter most and to timely and effectively address them under REACH and CLP.

In addition, one of the activities started in 2016 is the systematic review of the Roadmap implementation. This work will continue in 2017 and be reported in the annual report to be published in 2018. This review evaluates how far we are with the work on the different substance groups (or types of hazard properties) and the functioning of the tools set up and agreed to be used in the implementation.

More information on the roadmap and the roadmap implementation plan is available on ECHA's website[1].

Figure 1 gives an overview of all the activities and groups of the REACH and CLP machinery serving the SVHC Roadmap and ECHA's integrated regulatory strategy[2].

[1] Available at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

[2] Available at: https://echa.europa.eu/documents/10162/1564405/mb_59_2015_update_cch_en.pdf/713315f8-7cbd-4782-a0aa-53621615b965

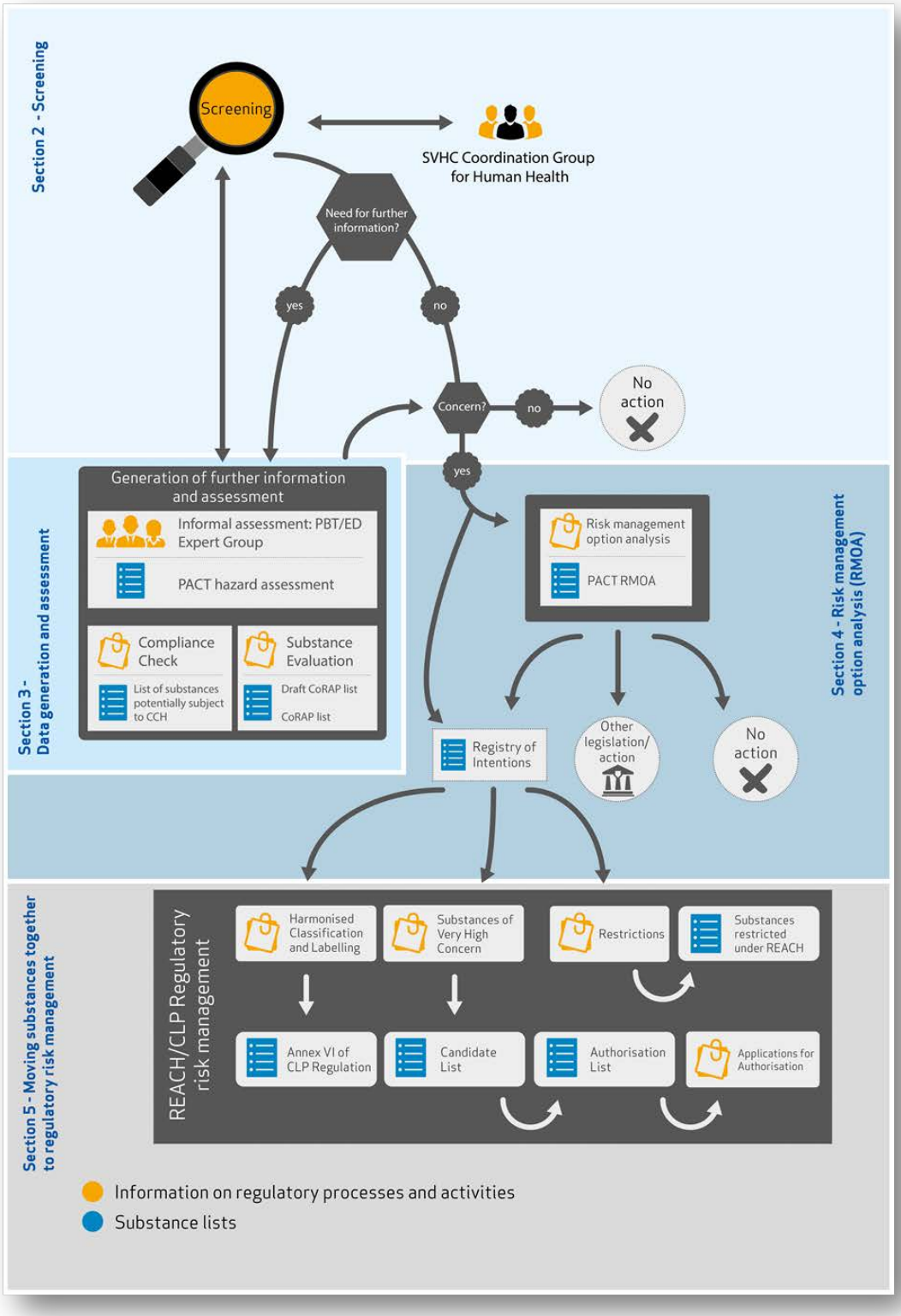
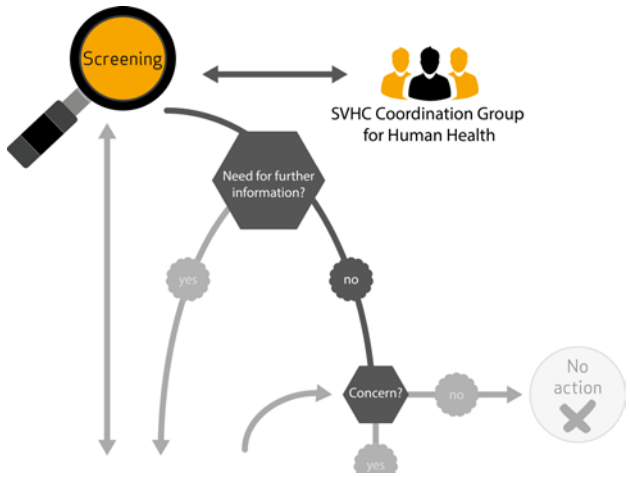


Figure 1: REACH and CLP machinery serving ECHA's integrated regulatory strategy and the SVHC Roadmap[3].

[3] Clickable version available at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-



2 Screening

Integrating REACH and CLP processes to provide a solid basis for identifying substances of concern.

Screening to find potential substances of (very high) concern is an important element of the SVHC Roadmap to 2020 implementation plan as well as an integral part of ECHA's integrated regulatory strategy to focus on the substances that matter most.

Bringing processes together

The common screening approach is now the main source feeding substances into REACH and CLP processes. These processes include compliance check, substance evaluation, authorisation and restriction under REACH, and proposals for harmonised classification and labelling under the CLP Regulation.

By placing the prioritisation of substances at an early stage and by grouping similar substances together, the different REACH and CLP regulatory processes are brought together, which ensures a more consistent way of approaching substances in the different processes and increased efficiency.

Compliance check has been further integrated into the common screening in 2016 with new scenarios developed to identify potential candidates for ECHA. Substances identified for compliance check are therefore nowadays the result of both Member States' manual screening and internal screening at ECHA. These are subject to the same prioritisation criteria as shortlisted substances with regards to exposure potential.

In the third round of screening carried out in 2016, 288 substances were added to the shortlist as a result of IT-screening and a further 17 substances were added by Member States as a result of their own national prioritisation. Of these 305 substances, 184 were picked for manual screening. As can be seen in Figure 2, the manual screening concluded that for about 72 % of substances follow-up action is needed. Some substances required two parallel regulatory actions so the number of outcomes is actually higher than the number of screened substances.

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concern

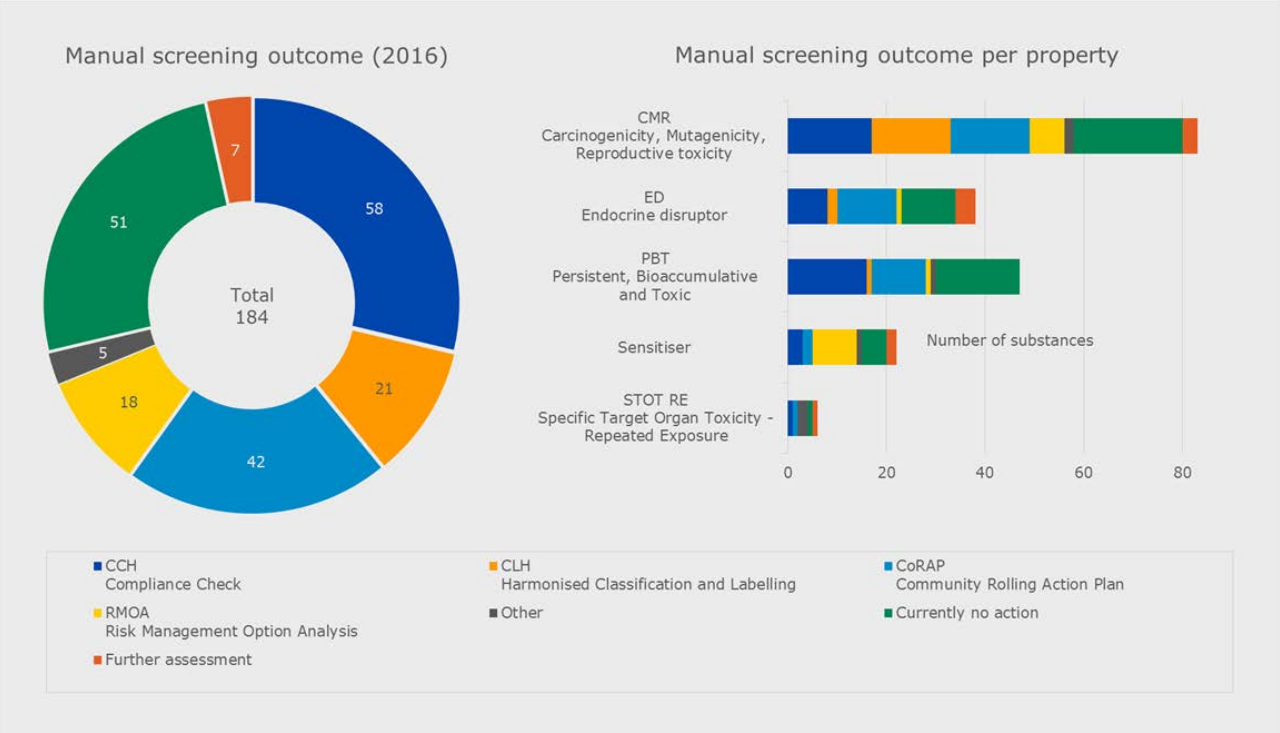


Figure 2: Manual screening outcome per process and per property (2016) [4]

Several substances for which 'currently no action' was indicated as an outcome are actually substances for which a pending action on a structurally-related substance is ongoing. This clearly shows the importance of looking at substances together (as a group of related substances) and not anymore as individual substances.

[4] Further assessment refers originally to further assessment of PBT and ED properties and consultation of the expert groups. However it has been recently used to further investigate equivalent level of concern cases, for instance.

Behind the numbers – Screening of skin sensitisers

Simple numbers do not always tell the full story. When poring over the manual screening results (as reported in the last few SVHC Roadmap annual reports) you will see that MSCAs have manually screened about 40 substances with a harmonised classification for skin sensitisation.

Given that there are about 800 registered skin sensitisers with a harmonised classification and that sensitisation is one of the concerns that the SVHC Roadmap specifies should be examined for possible SVHC identification, you might think that not much has been achieved so far.

But this would be short-sighted as it does not take into account other processes and activities, particularly the work done to prioritise substances before manual screening to focus the resources on those cases where further work can be expected to bring most added value for the protection of human health.

Of the 800 registered substances with a harmonised classification for skin sensitisation, about 600 have reported uses only at industrial sites, including many uses as intermediates under strictly controlled conditions. That leaves only 200 substances with potential widespread uses by consumers and/or professionals outside industrial settings.

But even that does not tell the full story, as many of these 200 or so substances are or have been under scrutiny in other processes. In fact, over 100 skin sensitisers have been included in manual screening, RMOA, CoRAP or on the Candidate List, although not for skin sensitising but other hazard properties. This leaves about 90 substances with potentially relevant uses, which have not yet been examined. That is a far cry from the 760 you could initially be led to believe.

In addition, few substances with only skin sensitising properties have been taken up so far for manual screening by Member States and/or moved to further regulatory action. If some respiratory sensitisers have been identified as equivalent level of concern to CMRs and placed on the Candidate List, this is not the case for skin sensitisers. However, other regulatory measures, such as restriction, have been proposed or initiated based on work carried out under previous legislation or national activities.

Even though not visible from the numbers, registered and harmonised skin sensitisers have been extensively scrutinised under the SVHC Roadmap and therefore systematic screening for skin sensitisers by ECHA is discontinued for the time being. Lists of remaining skin sensitisers are available for those Member States who wish to continue the work.

Bringing substances together

Over the last few years, ECHA and the MSCAs have manually screened hundreds of individual substances and many substances are either in one of our processes or recently regulated. It is becoming more common that when a new substance is identified for further work, a related substance has already been identified. ECHA has started to more actively identify these groups and relationships between substances.

Working with groups of substances from the start and helping Member States focus on substances with similar or the same properties as those they have worked on in the past will:

- increase efficiency and ensure a consistent approach to similar substances as we conclude for a higher number of substances within a shorter period of time;
- enhance the coherence of authorities' work through all steps from generation of further information (compliance check, substance evaluation, other means including direct contacts with industry) to regulatory risk management (harmonised classification and

labelling, SVHC identification and authorisation, restriction, but possibly also actions under other legislation);

- avoid unnecessary testing
- maximise the use of available resources by avoiding overlaps or gaps of activities; and
- provide transparency and predictability towards industry.

A grouping approach is also important to identify those substances, for which there is clearly less information available (e.g. only registration with intermediate uses or C&L notifications), but which could be potential substitutes to substances already identified for regulatory action.

These are called “supplementary activities” in the SVHC Roadmap Implementation Plan. The same applies for substances which are currently not on the EU market as such or in mixtures, but may be imported in articles. Without a grouping approach those substances would not be identified as early as needed to avoid regrettable substitution.

The shortlist of substances developed in 2016 for Member States to manually screen in 2017 has been developed around groups of substances and experience will be gained on how to handle those. This work will be one of the major developments in 2017 and beyond in identifying substances of potential concern.

Grouping can be done in many ways, structural similarity is one but we also use read-across and categories built by registrants as well as established categories developed by other bodies (e.g. the OECD).

Similar uses or functions can also be used to group substances and this will be further investigated in 2017. This work will need to be developed in close cooperation with Member States.

Manual screening will likely involve further refinement of the groups as the boundaries of the group may change throughout the different regulatory steps based on further information as well as the needs of each individual regulatory process.

Bringing actors of the SVHC Roadmap together

22 Member States participated in the third round of manual screening with two Member States participating for the first time (LU and SI). Not all Member States participate in every round. So far, 23 Member States have participated in manual screening. The number of substances screened per Member State is reported in Figure 3. Since the start of the common screening, 15 Member States have cooperated on over 20 substances sharing expertise and resources.

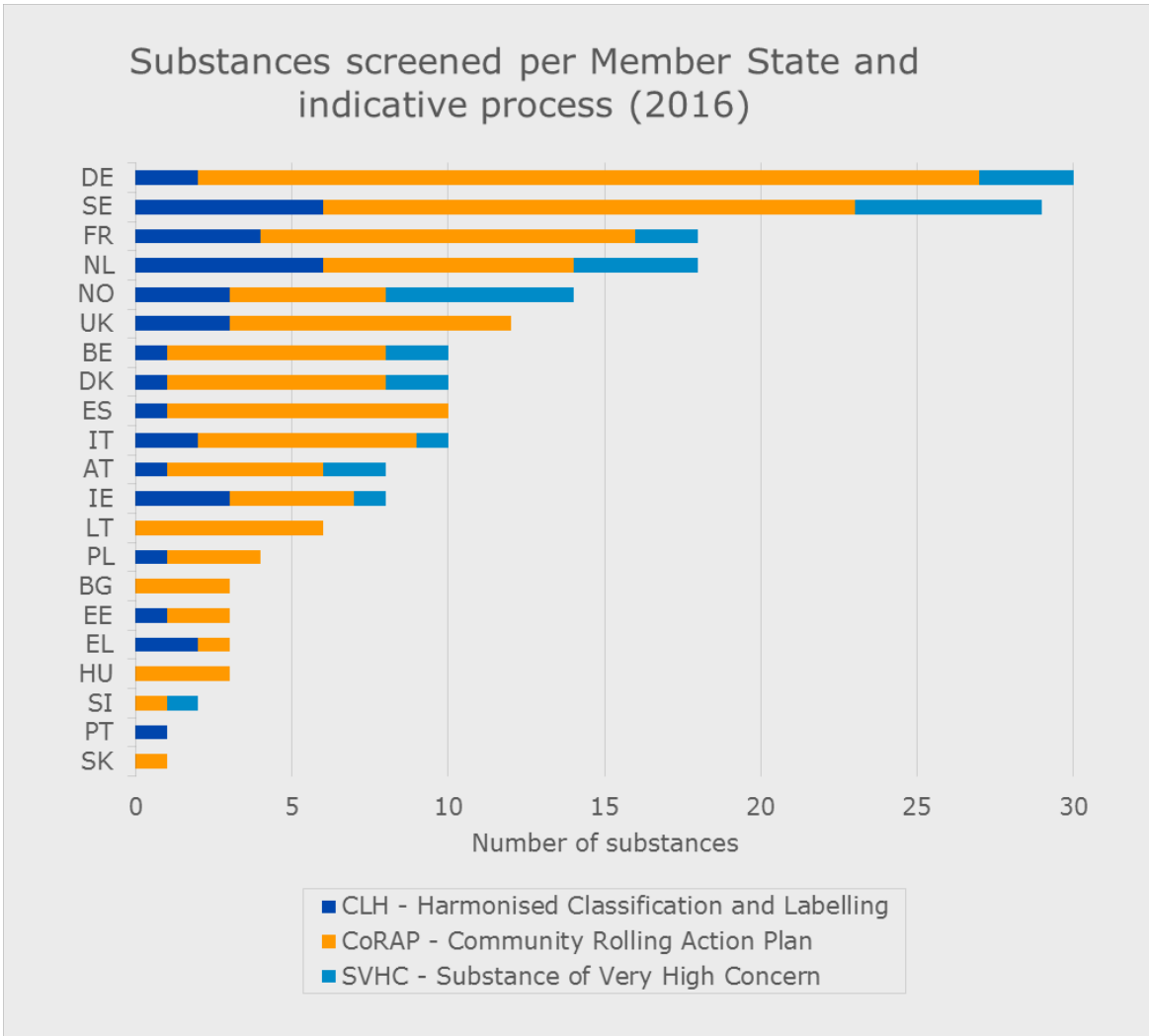


Figure 3: number of substances screened per Member State and indicative process in 2016.

As in previous years, ECHA ran a letter campaign for the substances shortlisted based on the IT screening in 2016. All registrants of the shortlisted substances were alerted to the fact that their substances might be under scrutiny by Member States and invited to review their dossiers with regard to identified potential hazards and their use and tonnage information.

They were also encouraged to review and update their substance identity information and any read-across they might have applied, if needed. The aim of this campaign is to increase the transparency and predictability of the screening process by letting registrants know that their substances were shortlisted as well as to trigger updates (40 % update in four months in 2016) of dossiers so that both authorities and registrants focus on the right substances. For instance, if some information on uses in the registration dossiers is not up-to-date, the exposure potential may be overestimated (see the Evaluation Report[5]).

Moving to working more with groups of substances will entail the need to bring people together as well. Different Member States will be brought together to collaborate on larger groups, sharing expertise and resources. Cooperation among registrants may also increase as well as cooperation

[5] Available at: https://echa.europa.eu/documents/10162/13628/evaluation_report_2016_en.pdf/f43e244f-7c90-75bd-e1b2-3771bcb1f8e8

between authorities and industry for some specific group of substances. One example of such cooperation is the petroleum and coal stream substances (PetCo) working group.

Working together on groups of substances - PetCo working Group

Petroleum and coal stream substances (PetCo) have very complex and variable/partly undefined composition (UVCBs). Those substances are of potential concern for human and environmental health due to their potential CMR and/or PBT properties, their high volume and the indication from the registration data that they are not just used as intermediates or in fuels, but also in other uses relevant for regulatory risk management.

For this group of substances, the SVHC Roadmap notes that there is first a need to develop an approach on how to address them. This is, as in past years, that these substances were put aside from the prioritisation and screening activities of authorities and NGOs due to their complexity. The PetCo working group was set up in 2015 to develop an approach to prioritise and address them and also to plan how to practically implement the approach. The group is composed of Member States, the Commission and interested accredited stakeholders.

PetCo substances are a clear example of a group of substances which need to be looked at in a holistic manner due to their similarity of structure and hazard. The approach developed allows lessons to be learned from the work done on a defined set of substances before looking at additional substances. This is to gain efficiency as those substances are so closely related and need to be looked at together to avoid duplicating work and potentially testing.

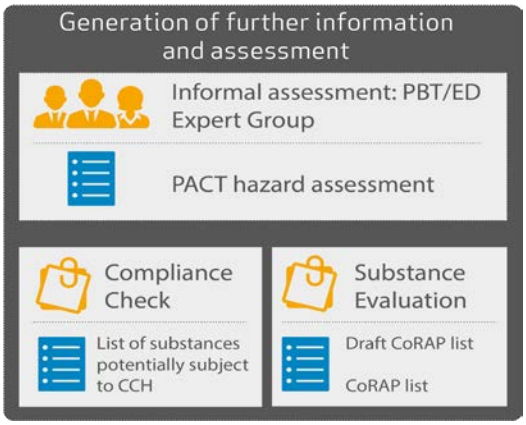
The main steps of the approach have been agreed and the working group will now move to the implementation phase. The starting point is to prioritise substances based on their uses. Substances used by consumers and at professional settings were prioritised to focus first on the substances which matter most for the follow up regulatory processes.

Substances used only as fuels and/or intermediates are considered to be of lower priority. Other than for intermediate uses, substances used at industrial settings are regarded as a medium priority. The second step in the approach is to consider the (potential) hazard of those substances where the benefits of looking at this group of substances together will be even more visible in the future and will ensure that substances of high but also low hazard concerns are identified.

Besides developing the approach, the work on PetCo substances has already been progressing at different levels such as updates of information on uses provided for petroleum substances (Concawe) and ongoing for other substances. In 2017, Concawe will provide updated dossiers containing updated information on uses. An inventory of all substances falling under the approach is also available and industry has committed itself to keeping this up-to-date. Parallel assessment and regulatory work has started and will progress in 2017.

Draft work plans on how to address those substances including a list of actions for the different actors have been developed and will be further discussed and followed up by the group in the future.

3 Data generation and assessment



Bringing expertise and processes together to ensure swift generation of data on substances of potential concern and to smoothen the further regulatory processes.

Bringing processes and expertise together

For most of the substances that are currently being looked at by the authorities to assess and confirm the SVHC properties, there is a need first to generate further information, go for further assessment and/or propose harmonised classification and labelling. Substance evaluation and compliance check are the main tools for generating missing hazard information.

Substances may be under different processes (as reflected in the numbers reported). However, in most cases, this work is done in parallel in an effort to use the best combination of the different tools to clarify the hazardous properties of those substances in as short time as possible. For instance, all substances planned in the CoRAP for future substance evaluation will undergo a compliance check to ensure that standard information is available and to verify further the need for substance evaluation to generate additional information. Compliance check and substance evaluation can also be conducted in parallel when suitable to shorten the time to clarify the concern. Consultation of the PBT and ED Expert Groups is usually done in parallel to substance evaluation to ensure a common understanding of the information to be generated before entering the decision-making stage of substance evaluation.

The substance-specific discussions under the expert groups[6] have supported the assessments of PBT and ED properties and made them fit better for regulatory purpose. Since those assessments are scientifically challenging, it is truly beneficial to be able to discuss those cases among experts. Experience has shown that this increases the consistency of the assessments, and that it smoothens and speeds up decision making under the substance evaluation and SVHC identification processes.

Around 85 % of the substances with potential PBT properties listed on the CoRAP[7] were discussed in the PBT Expert Group. Of the CoRAP substances under evaluation in 2016, all those with endocrine disruption as an initial concern were scheduled for discussion in the ED Expert Group, but as the evaluating Member State did not have sufficient resources to prepare the cases in time discussions only took place for around 60 % of them. All substances which Member States

[6] In addition to CoRAP substances, PBT and ED expert groups can discuss other substances including substances not in the scope of REACH (for example, biocides and veterinary medicine)

[7] Available at: http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

have proposed to include in the Candidate List due to their PBT and/or ED properties have first been discussed in the PBT and ED Expert Groups.

Besides the assessment of PBT and ED properties of substances, the two expert groups discuss how to improve methodological aspects of the assessment. An example of this work is the ongoing update of the PBT guidance.

Figure 4 gives an overview of substances under "generation of data and assessment" either via substance evaluation or discussions in the PBT or ED Expert Groups per Member. 24 Member States have been active so far in substance evaluation whereas the number of Member States contributing to the PBT and ED Expert Groups are 19 and 9[8] respectively.

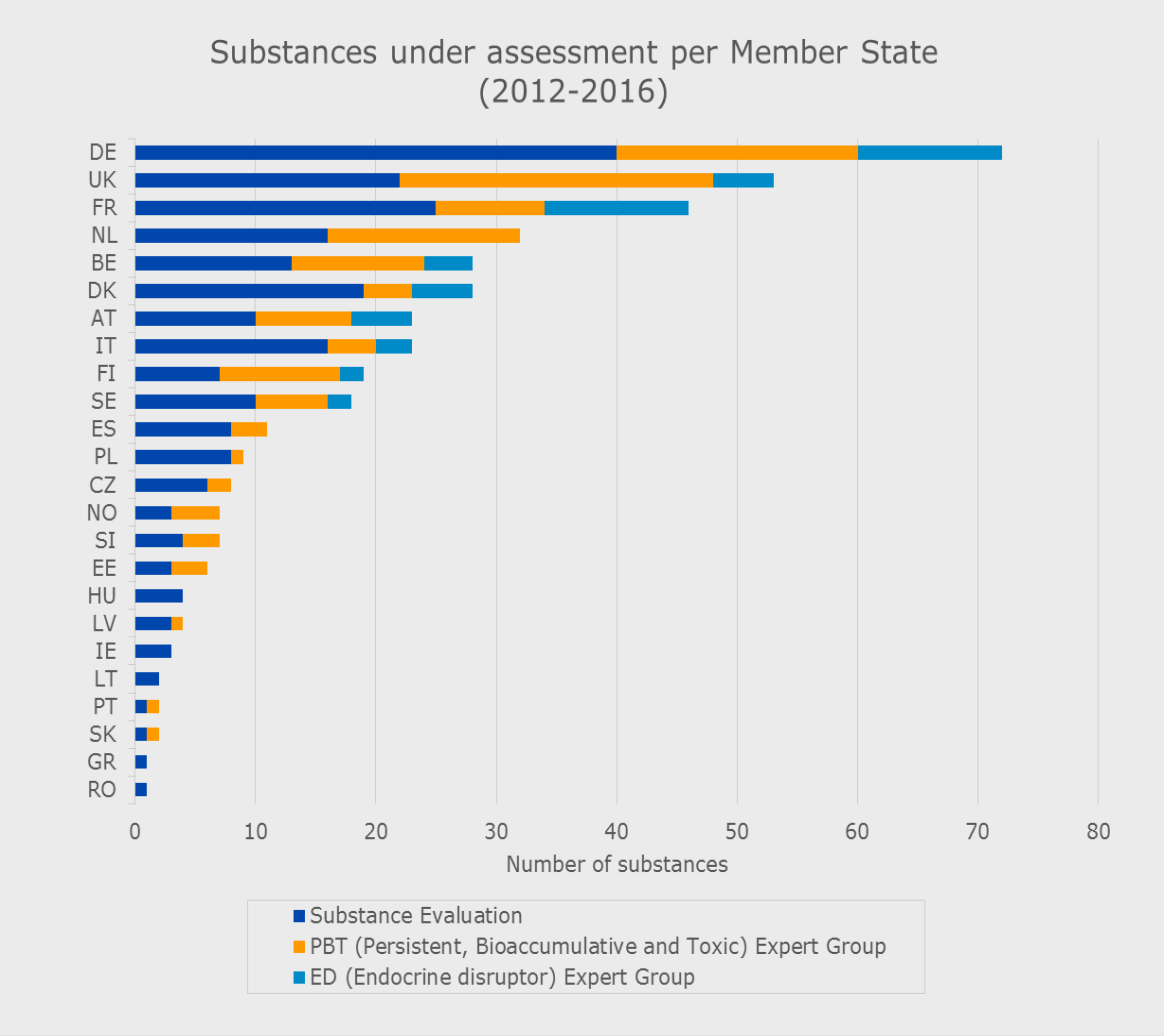


Figure 4: Number of substances under assessment per Member State in the ED Expert Group, PBT Expert Group and substance evaluation.

[8] 17 Member States participate to the ED Expert Group but so far only 9 Member States have brought substances for discussion.

Bringing numbers together

An overview of all substances under assessment from 2012, which corresponds to the set-up of the PBT Expert Group and the first cases under substance evaluation, until the end of 2016 is provided in Table 1 below. Some substances may be present and therefore counted under both substance evaluation and PBT/ED Expert Group. Note also that the ED Expert Group was set up only in 2014.

Table 1: Overview of the number of substances under PBT and ED Expert Group and substance evaluation (2012 - 2016)

	Ongoing assessment	Concluded assessments	Postponed assessment	Total
PBT Expert Group	109	38	11	158
ED Expert Group	34	13	1	48
Substance evaluation	172	49	-	221

In addition to the substances that are dealt with in substance evaluation and by the PBT and ED Expert groups, ECHA has since 2015 looked at 250 high priority substances (substances that matter) under compliance check[9]. For around 87 % of these substances the suspected concerns related to CMR and/or PBT properties. 67 of these are CoRAP substances for which substance evaluation has not yet been started.

A summary of the information requested in ECHA decisions in 2016 is provided in Figure 5 as reported in the Evaluation Report[5]. The first results of the follow-up evaluations of data received after the compliance checks of high priority substances will not be available before the end of 2017. More information on the outcome of compliance checks is available in the Evaluation Report[5].

[9] Substances on which ECHA has started a compliance check have been counted and not the number of dossiers.

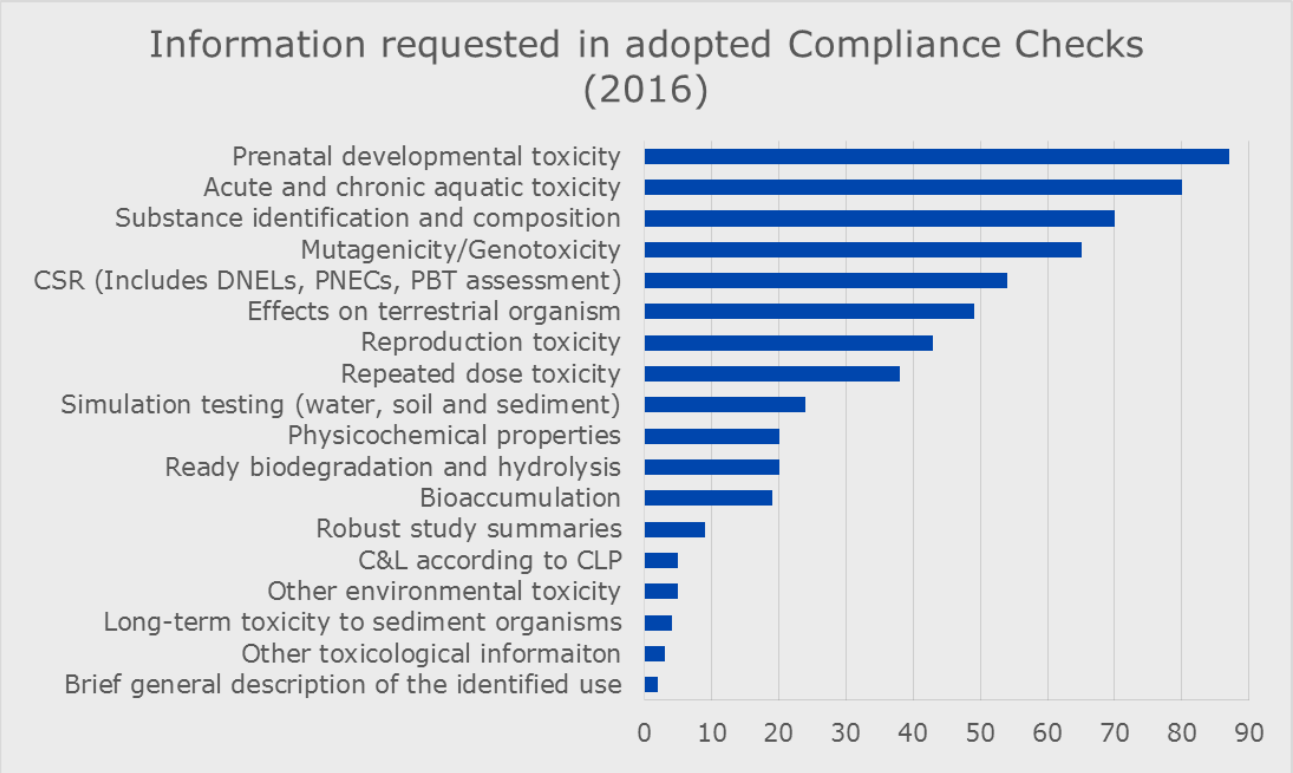


Figure 5: Information requested in the 152 adopted ECHA compliance check decisions taken in 2016 (Evaluation under REACH progress report 2016[5]).

Figure 6 provides an overview of number of substances which have been or are assessed for their CMR, PBT/vPvB, ED and sensitisation properties.

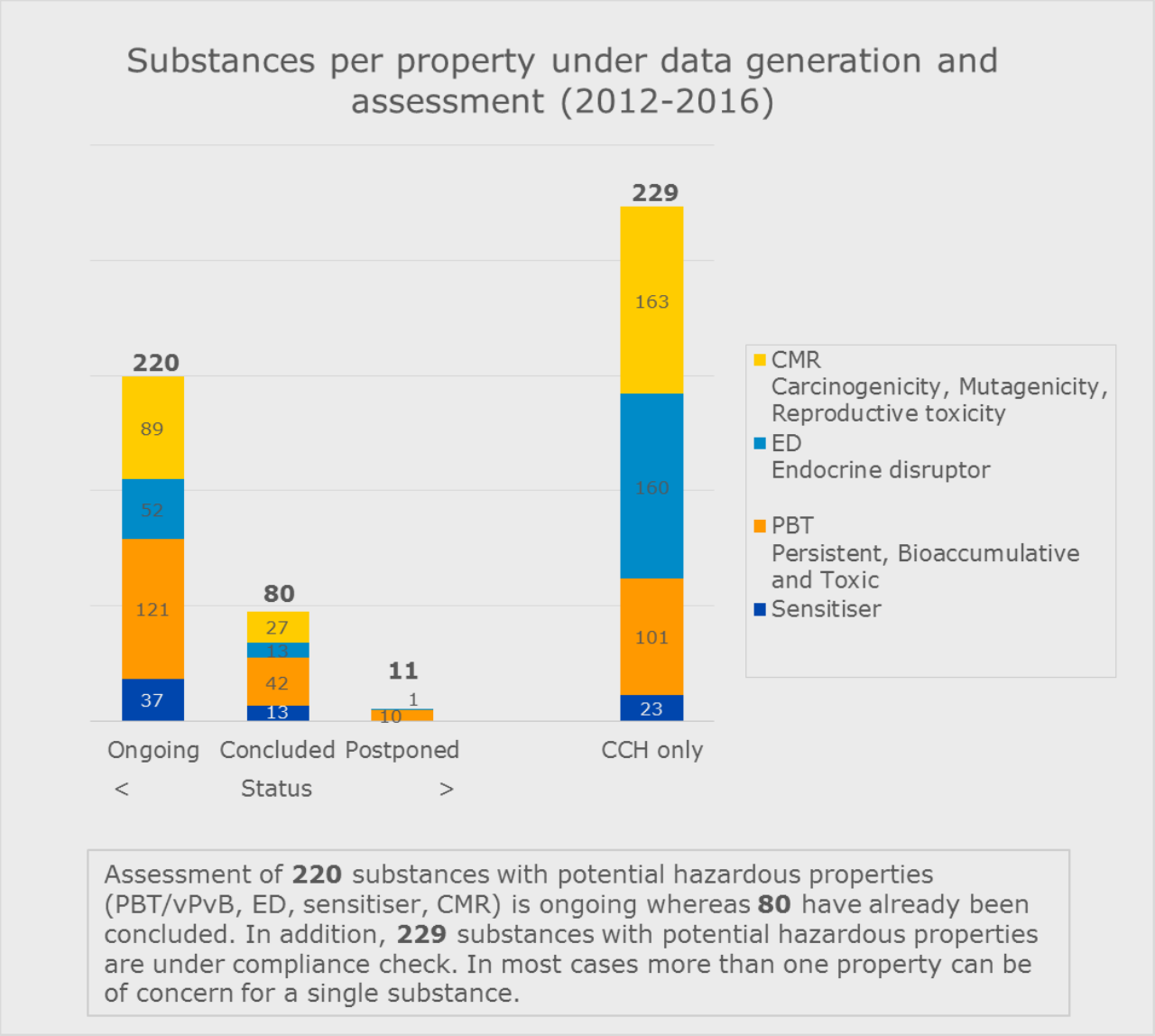


Figure 6: Substances and properties under "assessment" (2012-2016)

So far, the potential PBT/vPvB properties of 173 substances have been assessed under substance evaluation or discussed by the PBT Expert Group (or both of them). Similarly 73 substances with potential ED properties have been looked at. 116 CMRs and 50 sensitisers are (or have been) under assessment in the context of substance evaluation.

Under substance evaluation, in most cases more than one property can be of concern for a single substance (for example, one substance can be both a potential PBT and a potential CMR). Therefore, the total number of substances under each concern is not equal to the total number of substances under evaluation.

The final conclusion and confirmation on the PBT and ED properties can only be achieved through the SVHC identification process and inclusion on the Candidate List. Similarly for CMR and respiratory sensitisers, the final conclusion and confirmation can be achieved through the harmonised classification and labelling process and inclusion in Annex VI to the CLP Regulation. For further information on those processes, see section 5.

Behind the numbers – How many substances are under generation of data and assessment?

540 substances are under generation of data or assessment either in substance evaluation (CoRAP), compliance check or one of the expert groups or under more than one activity (e.g. both in the CoRAP and under assessment in the PBT/ED Expert Groups).

This number includes both ongoing assessments and concluded ones. Among the 540 substances, 311 are either under substance evaluation and/or one of the expert groups.

The remaining 229 substances are under compliance check and considered as ongoing assessment.

Moving substances together to regulatory risk management

CMRs with harmonised classification and PBT/vPvB substances identified prior to REACH have been considered by the authorities in previous years for further regulatory risk management as reported in the two previous annual reports[10]. In some cases, the authorities have concluded that they do not need further risk management. In all other cases, they are in the regulatory risk management processes – being identified as SVHCs, being subject to authorisation, having their classification harmonised, being restricted, or undergoing an analysis of the risk management options. New potential CMRs and PBT/vPvB substances are either under generation of data or assessment.

Tables 2 and 3 report on the number of substances for which a conclusion has been made on the hazard properties under assessment in the context of substance evaluation (Table 2) and the PBT/ED Expert Groups (Table 3).

As already highlighted in the annual report 2015, few substances have been concluded so far and among those very few fulfil the hazardous properties. Screening criteria need to capture potentially important borderline cases. Therefore, we also pick substances with weak indications of the PBT/ED properties. It is often possible to confirm that they do not fulfil the hazardous properties without further testing. Which is why the first concluded substance evaluation cases have often refuted the suspected properties (see Table 2).

The confirmation of suspected PBT/ED properties normally requires discussion on the best testing strategy and generation of data. The first conclusions for substances for which data were requested have been discussed in 2016, but more are expected to arrive from 2017 onwards.

[10] Available at https://echa.europa.eu/documents/10162/19126370/svhc_roadmap_2016_en.pdf/4c99ad17-fc00-48f1-9ada-5c5945ee7b83 and https://echa.europa.eu/documents/10162/19126370/svhc_roadmap_2015_en.pdf/38512385-2a46-455e-b2cd-3a52c1ad63f7

Table 2: Number of substances under substance evaluation and concluded per property and conclusions where relevant (2012 - 2016)

Property	Number of substances per property ongoing	Total number of substances per property concluded	Number of substances per property concluded	
			Considered to fulfil the hazard properties	Considered not to fulfil the hazard properties
PBT	69	16	0	15[11]
ED	49	11	2	8[11]
CMR	89	29	11 (2[12])	18
Sensitiser	37	17	13 (6[12])	4

Most of the substances discussed in the PBT and ED Expert Groups are substances under substance evaluation, which explains why so few substances are also concluded at that level. It should however be highlighted that once data are available, the process of identifying the substances as either PBT or ED can be very quick. For instance, three (groups of) substances that were discussed in the ED Expert Group in 2016 are already included on the Candidate List due to their endocrine properties.

Generation of data and assessment of suspected PBT/vPvBs takes time

In 2016, the first two cases of substances for which data requested under substance evaluation (CoRAP, 2012) were submitted by the registrant and brought by the evaluating Member States for discussion to the PBT Expert Group. Eight more cases (CoRAP 2012, 2013) for which new data was generated and recently submitted are expected to be discussed in 2017. For most of these substances the evaluating Member States proposed, in line with the available guidance, a tiered testing starting from persistency. After the first data submission, there may be another tier of testing for bioaccumulation and/or toxicity.

The data generation takes considerable time. Since over time PBT substances accumulate in the environment, the experience gained so far by ECHA and the Member States will be used to reduce the overall time spent to identify and regulate these substances.

[11] One substance has been suspended awaiting the outcome of another substance evaluation.

[12] 89 CMR under assessment, 29 concluded of which 11 considered to fulfil the hazard properties (among which 2 newly identified or classification upgraded) and 18 not considered to fulfil the hazard properties.
37 under assessment, 17 concluded of which 13 considered to fulfil the hazard properties (among which 6 newly identified or classification upgraded) and 4 not considered to fulfil the hazard properties.

Table 3: Number of substances concluded under the PBT and ED Expert Groups and conclusions where relevant (2012 - 2016)

Property	Number of substances ongoing	Total number of substances concluded	Number of substances concluded	
			Considered to fulfil the hazard properties	Considered not to fulfil the hazard properties
PBT Expert Group	109	38	1	37
ED Expert Group	34	13	8	5

One way to increase efficiency and speed up the process is to look at structurally-similar substances together from the screening onwards. Groups of substances are already being assessed during data generation and assessment processes (substance evaluation compliance check and PBT/ED Expert Groups) and this will most probably be strengthened in the future as screening moves towards working with groups of substances. This helps to ensure that the generation of data is done on those substances which can be used later on to clarify the properties of other structurally-related substances.

An example of working with groups of substances is the work ongoing on perfluorinated substances where in addition to covering several substances at a time the work done will ensure regrettable substitution is avoided.

Moving substances together – work on the group of PFASs

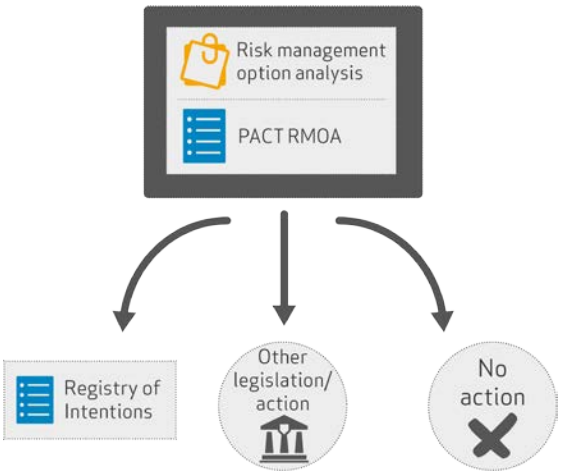
Seven long-chained perfluorocarboxylic acids (PFCAs) were identified as SVHCs between 2013 and 2016 (PBT or vPvB depending on the case). None of these are registered (yet) under REACH. However these substances are on the EU market in goods and found in the nature, living environment and also in humans.

SVHC identification can be used to restrict these substances in articles. It also gives a clear signal to industry that these are not suitable alternatives.

In addition, a high number of precursors of these PFCAs have been identified, which together with the PFCAs are the target of regulatory risk management work. The first restriction on part of the group ("PFOA"-related substances) is already agreed upon.

Due to the extreme persistence of the per- and polyfluoroalkyl substances (PFASs), exposure caused in the past will unfortunately remain in the environment for decades and for even longer. Learning from the experience on PFCAs, the short-chained PFASs (which are also extremely persistent), are now the focus of the joint work of the Member States, the Commission and ECHA to clarify their properties and move them forward to regulatory action, where necessary. The work on a handful of substances will be used to address tens, if not hundreds of precursors.

4 Risk management option analysis



Progress in identifying substances of concern for regulatory action, together with authorities and stakeholders

The purpose of a risk management option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and if so, to identify the most appropriate instrument to address a concern.

Sharing the RMOA early with other authorities allows them to give an early input on the information available, concerns and/or views on the benefits and drawbacks related to the use of different risk management instruments.

This in turn provides a better basis to decide on whether and how to proceed with further regulatory risk management (RRM) as well as input to drafting the RRM dossier. The RMOA process also allows early consideration and preparation by other authorities for the regulatory processes, which can lead to speeding up the formal opinion forming and decision making.

Furthermore, it can be used to increase transparency and predictability of authorities' work and by that help the stakeholders prepare for the regulatory processes.

Bringing authorities together

Since the start of the SVHC Roadmap in 2013, MSCAs and ECHA have been developing RMOAs for substances of potential concern, many of which have come from the manual screening process mentioned in Section 2. Implementing the RMOA concept follows a quite standard path, with the process positively received by interested parties.

Currently for 159 substances an RMOA is under development or concluded. 15 Member States have been represented in this RMOA work since 2013 when the work on the implementation of the SVHC Roadmap started. In some cases, RMOAs have been developed in cooperation between more than one member states. Figure 7 illustrates the split of the work on RMOAs per authority.

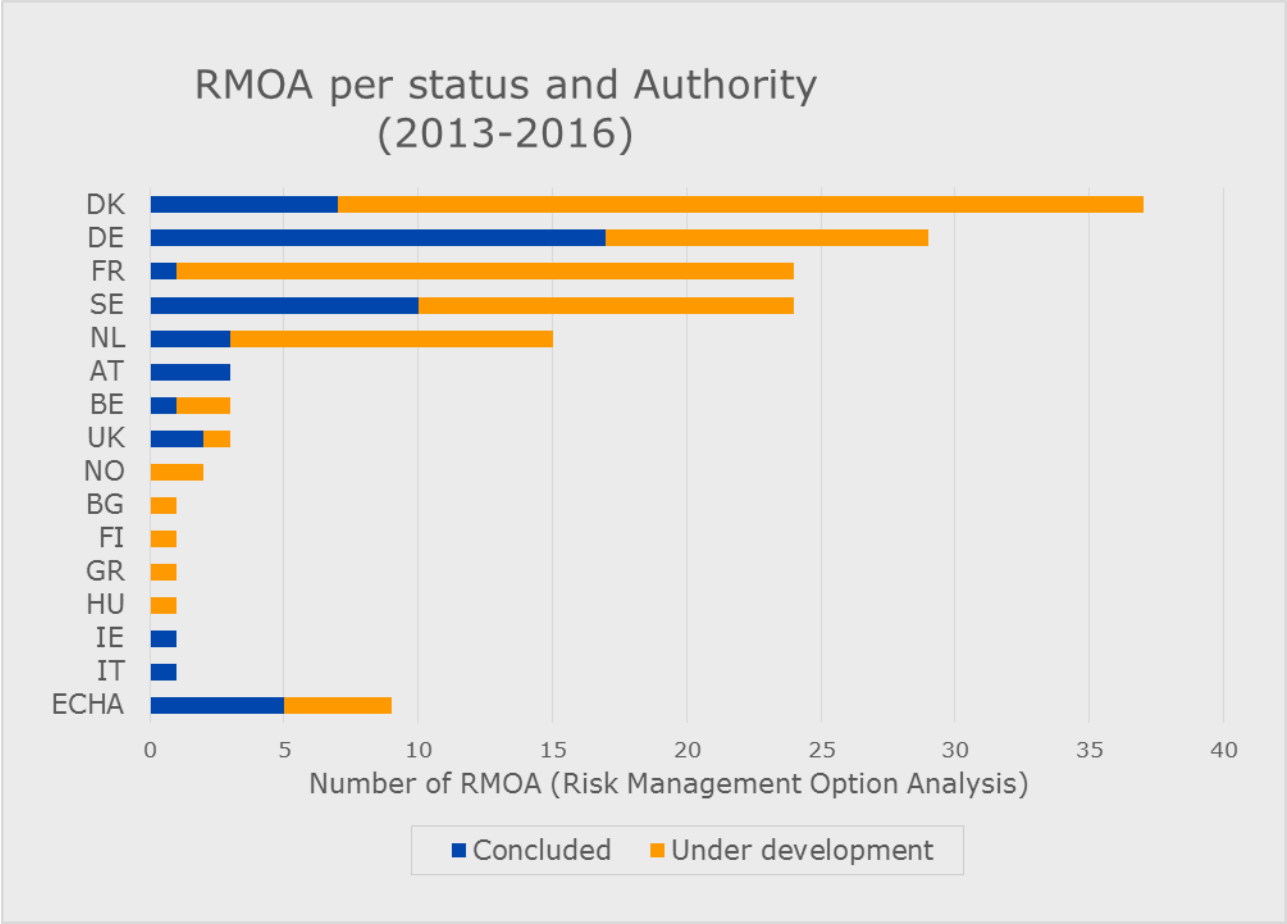


Figure 7: number of RMOAs per authority.

Platforms such as the Risk Management Expert (RIME) and SVHC Human Health Coordination[13] (SVHC CG HH) meetings play a role in bringing authorities together and ensuring these activities are coordinated. Authorities can exchange views through these platforms, which increases the common understanding on how to best regulate substances and adds harmonisation to the regulatory actions taken on (groups of) substances. One example is the discussion that took place on how to regulate substances containing impurities of very high concern which will be integrated in the overall review of the SVHC Roadmap implementation that started in 2016. This review and its outcome will be further reported in the next year annual report of the SVHC Roadmap in 2018.

[13] Both RIME and SVHC HH CG description are available at: https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern

Substances containing impurities of very high concern – an example of working together by authorities

The SVHC Roadmap increases the focus on potential SVHCs due to the presence of impurities, and calls for a more systematic identification and assessment of these cases.

The "SVHC Roadmap to 2020 Implementation Plan" foresees that the core screening activities should identify "(not yet scrutinised) CMR substances" and "sensitising substances" "which have harmonised classification due to group entries of Annex VI or due to constituents, impurities or additives which are in Annex VI".

In 2016, ECHA and 7 Member States (AT, BE, DE, DK, IE, NL, SE) worked together to focus on the issue of how to approach potential SVHCs due to their impurities, based on the experience gained so far.

Elements to consider when assessing the most appropriate risk management option for substances containing impurities of very high concern were defined. A non-exhaustive list of possible prioritisation criteria for selecting such cases was put forward.

Bringing substances together

The experience so far is that authorities have not only addressed individual substances in RMOAs but have also focused on some groups of substances due to similar hazards and/or uses.

The RMOA step supports cooperation among authorities who are looking at similar substances before entering one of the REACH/CLP processes. At the RMOA stage, authorities can share the workload, avoid overlapping work and ensure consistency of their actions on similar substances.

Figure 8 gives the number of RMOAs concluded or under development from the implementation of the SVHC Roadmap in 2013 to the end of 2016 per hazardous property. Some RMOAs cover more than one substance (e.g. lead and its compounds) or even a group of substances having the same hazardous property (e.g. skin sensitisers in textile articles).

For 67 RMOAs, a conclusion is available and for the remaining 92, the RMOA work is still under development. In 2016, 17 RMOAs were concluded and intentions for 16 new RMOAs were indicated.

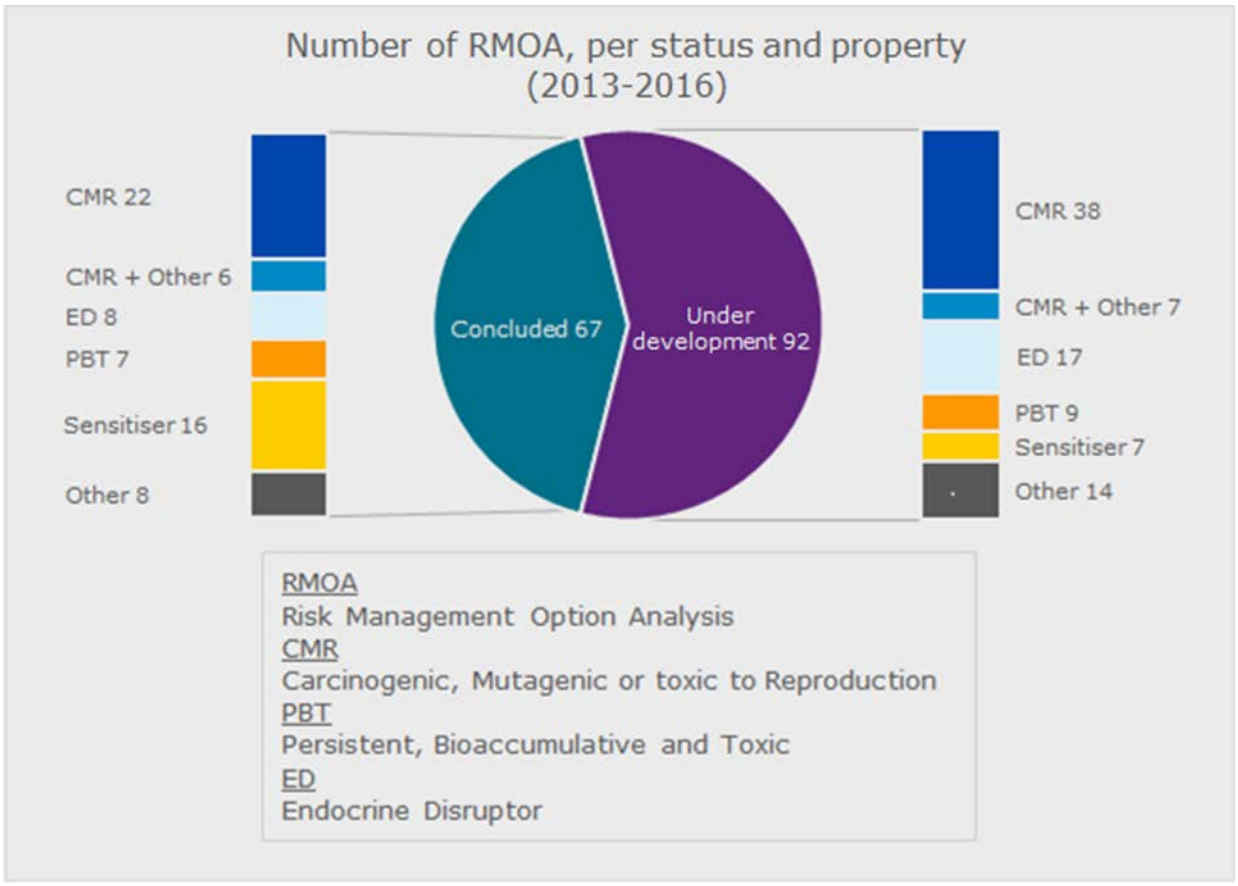


Figure 8: Number of RMOAs concluded and under development per hazardous property (February 2013 – December 2016[14])

The majority of RMOAs are still for CMR substances with a harmonised classification. However, the number of RMOAs investigating substances with ED and PBT properties has been increasing steadily for two years now. On the contrary, the number of RMOAs analysing substances with sensitising properties is reducing.

As more and more substances progress under either substance evaluation, compliance check or in the PBT and ED Expert Groups, the number of RMOAs covering substances with those properties can be expected to continue to increase. However, it should be kept in mind that, as the generation and assessment of information often takes substantial time, it will also take more time before the RMOAs can be concluded as reflected also in section 3.

RMOAs are also developed for groups of substances. Examples of such groups are the RMOA submitted on skin sensitisers in textile articles or the RMOA on isocyanates submitted by Germany for which the outcome was the need to restrict this group of substances due to their same hazardous properties and uses.

In 2016, 4 of the 16 new intentions to initiate an RMOA were for groups of substances. They are C9-C14 PFCAs including their salts and precursors; perchloric acid and its salts; skin sensitising substances in textile articles; and phenol, dodecyl-, sulfurised, carbonates, calcium salts.

The lower number of new RMOAs intentions in 2016 is partly due to the fact that for many cases further hazard information is needed to confirm the concern first. Furthermore, common screening was not yet in place when the SVHC Roadmap was agreed. MSs are currently able to

[14] The data reported in the table are until the latest update of PACT in 2016 (20 December 2016).

better select cases to the RMOA and those which do not merit the assessment of risk management options are concluded already in screening phase. Nevertheless the overall number of RMOAs is substantially less than originally anticipated in the SVHC roadmap. Further discussion with Member States and the Commission is foreseen to identify the reasons for this difference compared to the original ambition and agree on how to address the situation.

RMOA on a group of substances - skin sensitisers in textile articles (started and completed in 2016)

The RMOA on skin sensitisers in textile articles has the potential to have a wider regulatory impact. The bigger picture behind this RMOA is the possible future regulation of approximately 20 substances classified as skin sensitisers used in textile articles.

Helen Klint from the Swedish Chemicals Agency (Kemi) explains that the decision to conclude the RMOA suggesting restriction as the most appropriate regulatory risk management was made in the knowledge that not all of the information needed for a restriction proposal has been gathered or analysed yet, at the RMOA stage.

Kemi believes it is more beneficial to communicate the preliminary RMOA conclusion at as early a stage as possible, rather than waiting until all information is gathered/analysed before concluding the RMOA. A more comprehensive data gathering and analysis exercise will take place as part of the preliminary steps towards preparing a restriction proposal.

Kemi will revisit the RMOA at the beginning of 2018 to reflect a more final decision on whether or not to move forward with a restriction proposal. This will also take into account progress with restrictions proposals for CMRs in textile articles (COM) and tattoo inks (ECHA).

Link: https://www.kemi.se/files/8040fb7a4f2547b7bad522c399c0b649/report6-14-chemicals-in-textiles.pdf.

Bringing processes together

There are several potential sources of RMOA candidates e.g. from manual screening or substance evaluation, both of which are carried out by Member State competent authorities (MSCAs). RMOA can also reflect the outcomes of the hazard assessment done in the context of the PBT and ED Expert Groups. Therefore, RMOA sits at the interface between screening/substance evaluation/hazard assessment and regulatory risk management. RMOA can also come before or after the harmonised classification and labelling process. In addition, RMOA thinking can and should be embedded in the whole process starting from screening. The RMOA will evolve as the substance moves from one step to the next.

Interlinks between the ED Expert Group, RMOA and cooperation between authorities

The Austrian work on the environmental endocrine disruptor assessment of heptylphenol progressed in parallel with the elaboration of the RMOA, in collaboration with Germany. The ED assessment was based on data for heptylphenol itself and on a read across to four very similar alkylphenols that had been assessed as endocrine disruptors by Germany.

Running the ED assessment and RMOA processes in parallel worked well, as the conclusion on the hazard of a substance is one part of the RMOA. While the ED assessment progressed independently from the RMOA work, the RMOA depended on the result of the ED assessment.

The working assumption for the RMOA was that the ED criteria would be fulfilled for the substance. The right timing of discussions in the ED Expert Group (through written procedure) and RiME was important to get the most benefit from both consultations.

Discussions on substance identity during the ED assessment phase also led to a broader scope in the SVHC identification (group entry for all 4-heptylphenols, branched and linear), which was identified as the best risk management option in the RMOA.

The whole process of RMOA in combination with ED assessment took longer than a usual RMOA. However, Austria was able to finalise the ED assessment, RMOA and the SVHC dossier within 10 intense months of work, which was shorter than if the steps had been taken in sequence.

The fruitful cooperation with the colleagues from Germany was very helpful during the different phases of this work.

Using the RMOA approach from the start and updating the RMOA once new information is available, helps to identify the best combination of processes for each case. It also reduces the number of steps and overall time needed to conclude on whether or not the (group of) substances require further regulatory risk management and which option to take.

Table 4 provides the number of RMOAs concluded per proposed follow-up regulatory action at the end of each year since the start of the SVHC Roadmap.

For almost half of the substances (24), the proposed follow-up was identification as an SVHC. This is similar to what was already observed last year and confirms that the impact of the SVHC Roadmap starts to be visible particularly in identifying SVHCs.

The number of RMOAs concluding on the need for other EU legislation and/or other measures has also increased, which confirms that the RMOA tool is open and can in practice serve other legislation than regulatory risk management under REACH and CLP.

Table 4: Cumulative number of RMOAs concluded per proposed follow up regulatory action (February 2013 - December 2016)	By end of 2014	By end of 2015	By end of 2016
SVHC identification (authorisation)	5	16	24
REACH restriction	1[15]	5	6
CLH	1	2	4
Other EU-wide regulatory action	2	3	5
Other (e.g. non EU-wide and/or non - regulatory actions)	1	2	3
No follow-up action	5	11	15

Varying RMOA development time

There is no deadline for performing an RMOA. It can be initiated by an authority at any point and the time it takes to carry out the RMOA can vary.

The main factor contributing to the time it takes is the complexity of the case. If the hazardous properties of the substances need to be assessed, this can take longer than with cases where the hazardous properties are already known. Consultation with industry and cooperation between the MSCAs can also lead to more time being needed, however this additional time is generally felt to be time well spent.

Sometimes it can be difficult to conclude on the best RMO for substances, considering the specificities of the case itself. Resources available at the start of an RMOA may also be re-allocated to tasks with regulatory deadlines, for example. Priorities in authorities can also change, which can mean that the focus is sometimes moved to substances of higher priority.

Engaging stakeholders

Stakeholders can follow the substances undergoing RMOA in the Public Activities Coordination Tool (PACT). This provides increased transparency and greater predictability. Anyone who wants to know when a substance is on an authority's radar for regulatory risk management can find this information at a very early stage.

Stakeholders can see what substances are being analysed for possible further risk management before they become part of a formal risk management process, for example, harmonised classification and labelling, SVHC identification or restriction. Early awareness that a substance may be taken down a risk management route enables companies to assess how they are using the substance and whether or not it is possible to replace it with a safer alternative. It also gives

[15] One RMOA covering 11 substances, which is the reason why it is indicated as one only, even though there are 11 entries in PACT.

more time for interested parties to prepare to contribute to the public consultations, which are run during the formal risk management processes. Anyone with data on the substance, information on safer alternatives or other material will have more time to prepare. Registrants also have the chance to make sure that their registration data is up to date.

Another consequence of publication in PACT is that MSCAs are consulting with industry representatives, stakeholders and national institutions/government departments. The benefits of working together with industry during the RMOA stage have clearly been highlighted by both authorities and industry Whereas this can prolong the time it takes to develop the RMOA, this additional time is generally felt to be time well spent.

Consultation of stakeholders by authorities – The example of Germany

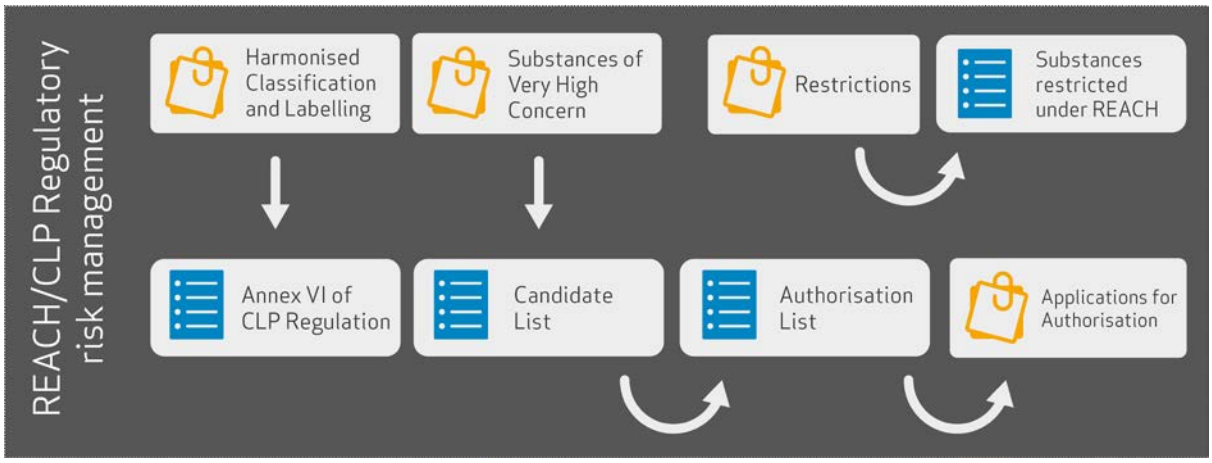
The Federal Institute for Occupational Safety and Health (BAuA) makes every effort to engage with industry during the RMOA stage by opening a consultation on the German RMOAs under development from their Helpdesk web pages. Frauke Averbeck from BAuA explains it is important that there is a balance between effective RMOA work by authorities and transparency.

For the German competent authority, the main benefit of these consultations is the valuable information received, which Frauke explained can often be useful to understand the potential exposure to or release of the substance. Additional information received can also give a "feeling" about alternatives and what the consequences of taking particular regulatory risk management action are. This can be very valuable at the RMOA stage in order to arrive at a sound conclusion.

Feedback suggests that BAuA's efforts to consult during the RMOA drafting stage, are very much appreciated from a transparency point of view.

Link: http://www.reach-clp-biozid-helpdesk.de/en/REACH-en/SVHC-Roadmap-en/DE_RMOA-Liste-en/DE_Stoffliste-en.html.

5 Moving substances together to regulatory risk management



The Commission has defined the SVHC Roadmap as a roadmap which will form a strong basis for further work of all authorities together on SVHC assessment and identification beyond 2020, but which also should ensure progress in other areas of REACH (for instance, restriction). Therefore, the picture would not be complete if the regulatory follow up steps were not reported.

An RMOA could result in different follow up REACH and CLP regulatory risk management processes such as SVHC identification and inclusion on the Candidate List for eventual inclusion in Annex XIV (Authorisation List), restriction or harmonised classification and labelling proposals.

Regulatory risk management activities are reported since the entry into operation of REACH in 2008. The impact of the SVHC Roadmap on regulatory risk management activities in the early stages of implementation needs to be interpreted cautiously as part of the regulatory actions outlined below may still result from screening/RMOA activities before the SVHC Roadmap was implemented.

In most cases, there will be a delay in time between when an RMOA is concluded and the actual start of a formal regulatory process. Moreover, the initial conclusions of an RMOA for a given substance or group of substances can be updated with newly available information and/or further considerations by a Member State/ECHA (at the request of the European Commission).

Member States may also carry out an RMOA outside of the SVHC Roadmap implementation context (for example, as a result of a national programme/national priorities). Additional information on regulatory activities is available on a yearly basis in ECHA's General Report[16].

5.1 Harmonised classification and labelling

Substances which fulfil the criteria for carcinogenicity, mutagenicity, reproductive toxicity or respiratory sensitisation in any category, should normally be subject to harmonised classification and labelling (CLH). Classification of active substances in biocidal or plant protection products (BPs and PPPs) should also be harmonised. For all other hazardous substances, a harmonised

[16] Available at: http://echa.europa.eu/about-us/the-way-we-work/plans-and-reports

classification and labelling can be sought, if a justification is provided that shows such an action is required at an EU level.

Figure 9 reports the number of proposals adopted by the Committee for Risk Assessment (RAC) from 2009 until December 2016 and Figure 11 shows the number of proposals submitted during the same period. Numbers are further broken down into proposals for active substances in biocidal and plant protection products (BPs and PPPs) and other substances, mainly those subject to REACH registration. As can be seen, the majority of substances subject to CLH are active substances in PPPs/BPs. The number of REACH substances for which a classification for new[17] and existing CMRs[18] was adopted is also reported.

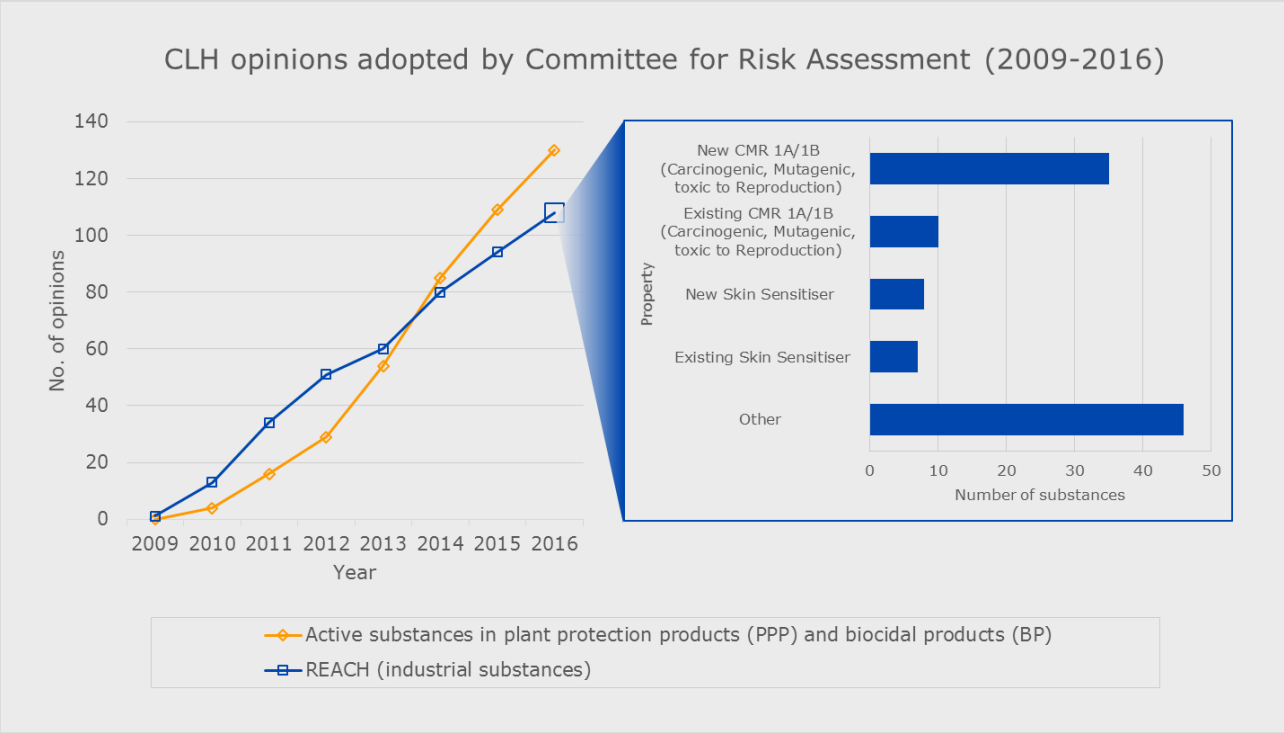


Figure 9: Numbers of CLH opinions adopted by RAC from 2009 – December 2016 and a breakdown of REACH substances for which a CMR 1a or 1b and/or sensitiser proposals was included.

Figure 10 gives an overview of Annex VI CLH dossiers submitted by each country.

[17] New CMR means the substances were not classified as CMR before.
[18] Existing CMR means the substances were already classified as CMR and the proposal was to amend something other than the CMR classification.

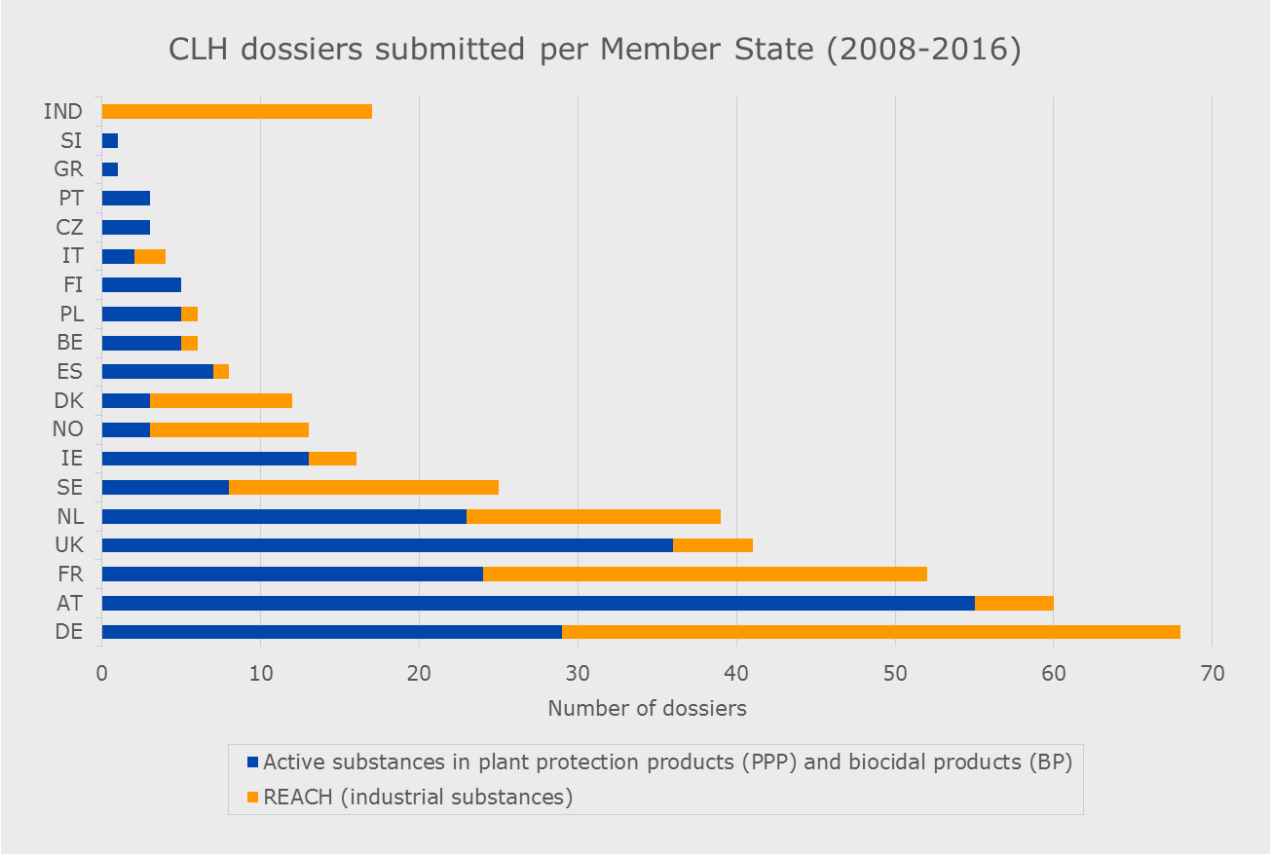


Figure 10: Number of CLH proposals submitted per Member State (2008 – December 2016)

5.2 Restrictions

Restrictions limit or ban the manufacture, placing on the market or use of certain substances that pose an unacceptable risk to human health or the environment.

A Member State or ECHA, at the request of the European Commission or on its own initiative in certain circumstances, can propose restrictions if they assess there is a risk that is not adequately controlled and there is a need for action at the Union level.

Table 5 gives the number of restriction proposals adopted or going through the restrictions process from 2009 until December 2016.

Table 5: Number of restriction proposals adopted or going through the restriction process					
Step	**PBT**	**ED**	**CMR**	**Sensitiser**	**Other**
Restrictions included in Annex XVII	1	1	7	2[19]	1
Restriction process ongoing	0	0	1	0	1
Sent to Commission, but not yet in Annex XVII	2	0	1	0	1
Total (only the ones with substance scope in RoI)	**3**	**1**	**9**	**2**	**3**

Figure 11 gives an overview of Annex XV restriction dossiers submitted per country.

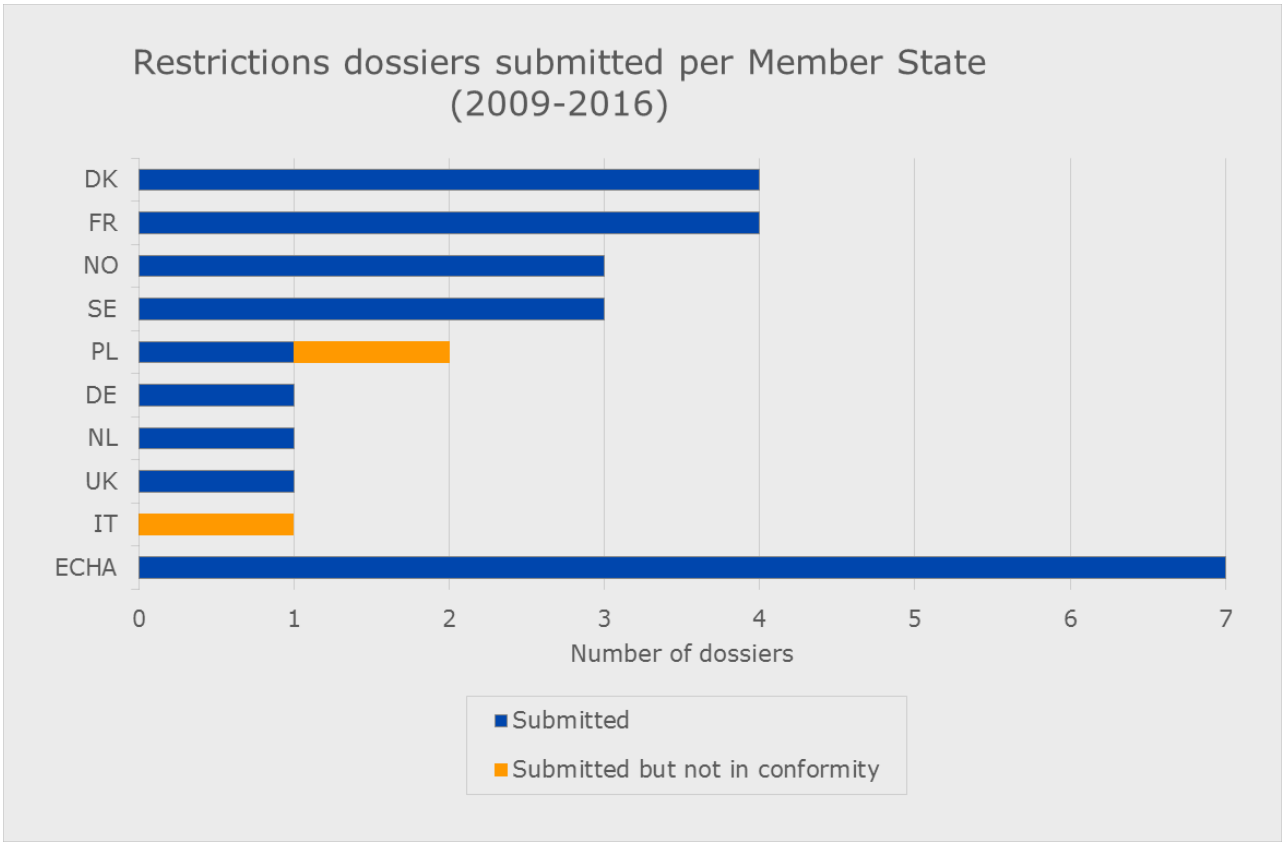


Figure 11: Number of restriction dossiers submitted per Member State and by ECHA (2009 – December 2016)

[19] One of the substances restricted is Chromium VI which is also a CMR substance, but is only considered here as a sensitiser as it is the scope of this restriction "Chromium VI in leather articles".

5.3 Authorisation process

5.3.1 Introduction

In 2008, the first substances of very high concern (SVHCs) under REACH were identified marking the start of the REACH authorisation process[20].

Figure 12 gives an overview of the number of substances identified as SVHCs, recommended for inclusion in the Authorisation List (Annex XIV) and finally included on the Authorisation List from 2008 until the end of 2016. These numbers are further explained below in their respective sections.

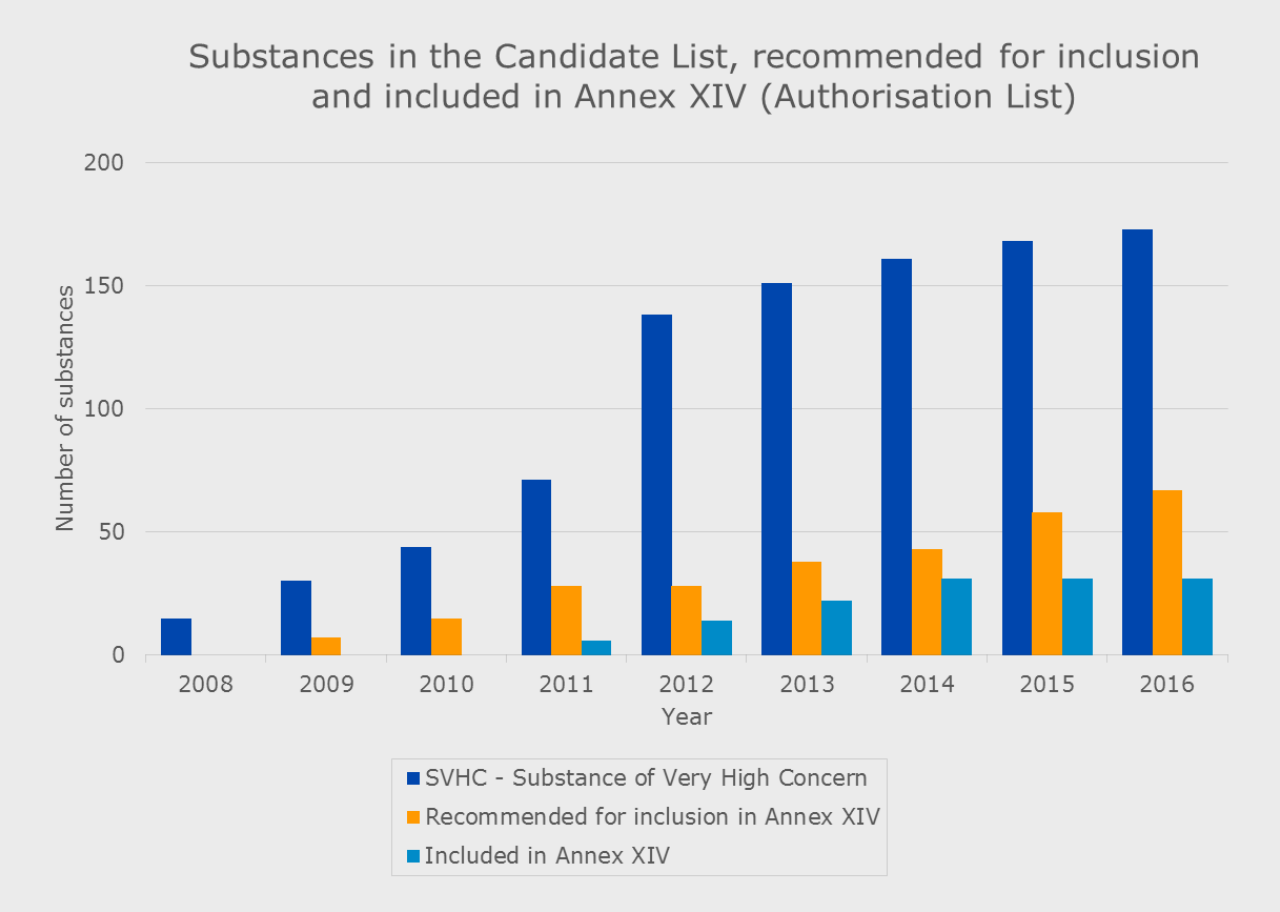


Figure 12: General overview of the number of substances on the Candidate List, recommended for inclusion in Annex XIV (Authorisation List) and included in Annex XIV.

5.3.2 SVHC identification

A Member State or ECHA, at the request of the European Commission, can propose a substance to be identified as an SVHC. SVHCs:

- meet the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR) (category 1A or 1B);
- are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB); or

[20] For more information on authorisation see: http://echa.europa.eu/regulations/reach/authorisation

- are identified on a case-by-case basis for which there is scientific evidence of probable serious effects that cause an equivalent level of concern to CMR or PBT/vPvB substances.

If identified as an SVHC, the substance is added to the Candidate List. The Candidate List includes candidate substances for eventual inclusion in the Authorisation List (Annex XIV). Furthermore, inclusion of a substance on the Candidate List creates legal obligations for companies manufacturing, importing or using such substances, whether on their own, in mixtures or in articles.

Since 2008, 173 substances have been identified as SVHCs and included on the Candidate List. The properties leading to inclusion on the Candidate List are listed in Figure 13. Some substances cover more than one hazardous property as illustrated below.

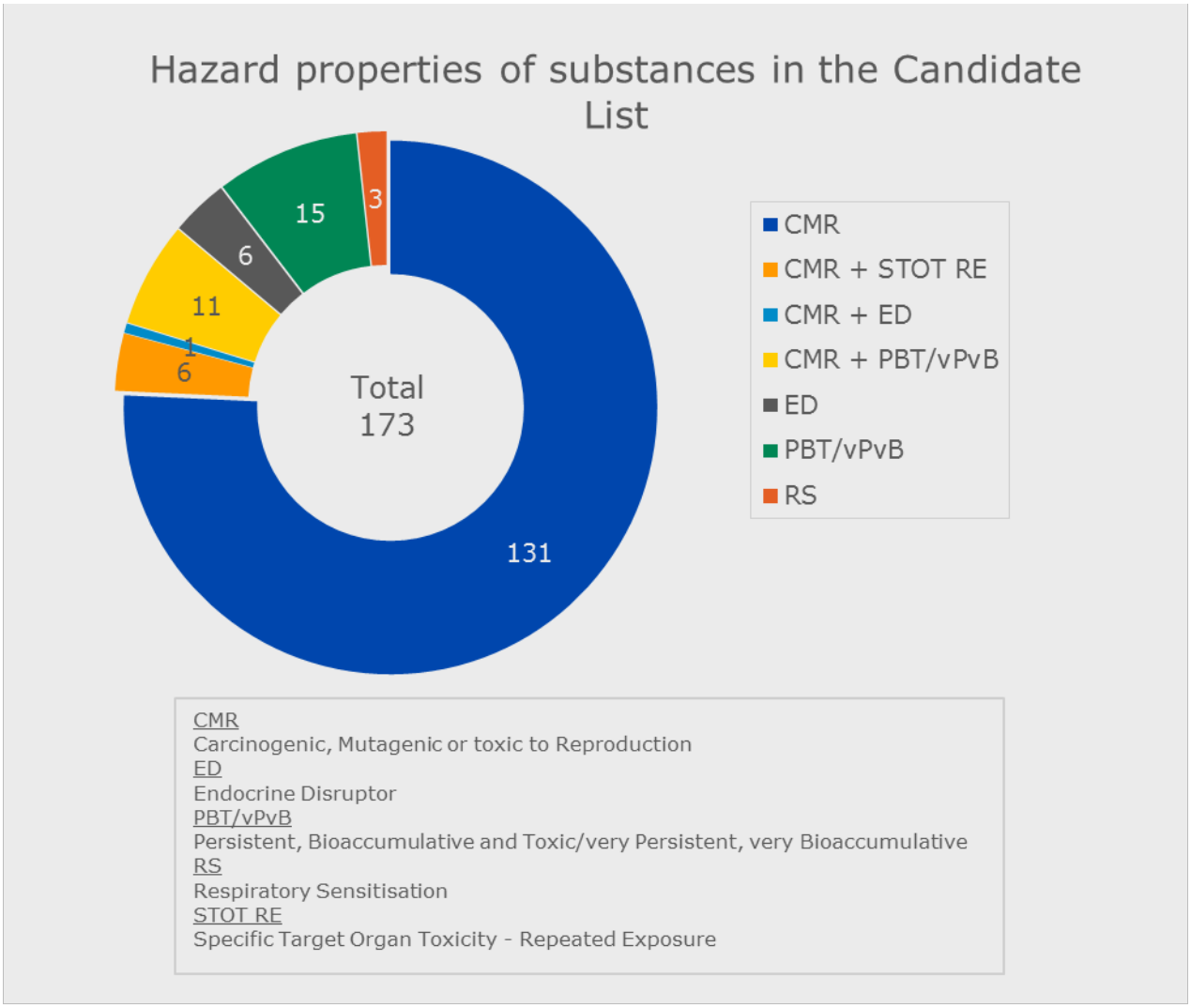


Figure 13: Substances on the Candidate List and overview of their hazardous properties

In 2016, five more substances have been identified and included on the Candidate List while the Member State Committee (MSC) could not reach a unanimous agreement on four cases which were then sent as MSC opinions to the European Commission for final decision-making (see Table 6).

Table 6: SVHC proposals discussed in 2016 and their outcome.	
Substances added to the Candidate List in 2016	
4,4'-isopropylidenediphenol (bisphenol A; BPA)	Toxic for reproduction
Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts	Toxic for reproduction PBT
p-(1,1-dimethylpropyl)phenol	Endocrine disrupting properties - environment
4-heptylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 7 covalently bound predominantly in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]	Endocrine disrupting properties - environment
Benzo[def]chrysene (Benzo[a]pyrene)	Carcinogenic Mutagenic Toxic for reproduction PBT vPvB
Cases on which the MSC could not reach unanimous agreement in 2016	
1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one (3-benzylidene camphor, 3-BC)	Endocrine disputing properties - environment
4-tert-butylphenol (PTBP)	Endocrine disputing properties - environment
Dicyclohexyl phthalate	Endocrine disputing properties – human health
Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride, TMA)	Respiratory sensitising properties - human health

One case (hexamethylene diacrylate (HDDA), EC: 235-921-9) sent to the Commission for final decision making in 2015, was decided[21] not to be identified as an SVHC in 2016.

Among the substances being concluded as fulfilling article 57(f) several cases are due to endocrine disrupting properties, which highlights that such substances can be identified by the Member State Committee and moved forward to further regulatory action.

In the first years of the existence of the candidate list inclusions were based on the already confirmed hazard properties, i.e. CMRs with harmonised classification and PBT/vPvB substances identified prior to REACH. Since 2012 the number of CMR substances included per year has reduced while the number of other substances has stayed at a similar level or slightly increased.

[21] Implementing Decision (EU) 2016/2091: https://echa.europa.eu/documents/10162/e972b773-7541-e9a7-4a85-4e209f0e5e97

This change relates to the fact that most substances for which potential concerns are identified first need further data generation and assessment before conclusions on their SVHC properties can be drawn (see also section 3 and the 2015 and 2016 annual reports). It can be expected that the new information generated via evaluation processes will bring new substances to the SVHC identification in coming years.

Table 7: Overview of number of substances included in the Candidate list per properties (2008 – 2016)[22]

	2008	2009	2010	2011	2012	2013	2014	2015	2016
CMR	8	7	16	25	59	7	5	3	1
PBT/vPvB	5	6	0	0	5	2	2	4	2
ED	0	0	0	1	2	1	1	0	2
STOT RE	0	0	0	0	0	3	3	0	0
Resp. Sens.	0	0	0	0	3	0	0	0	0
Total	**13**	**13**	**16**	**26**	**69**	**13**	**11**	**7**	**5**

Figure 14 gives an overview of Annex XV SVHC dossiers submitted per Member State.

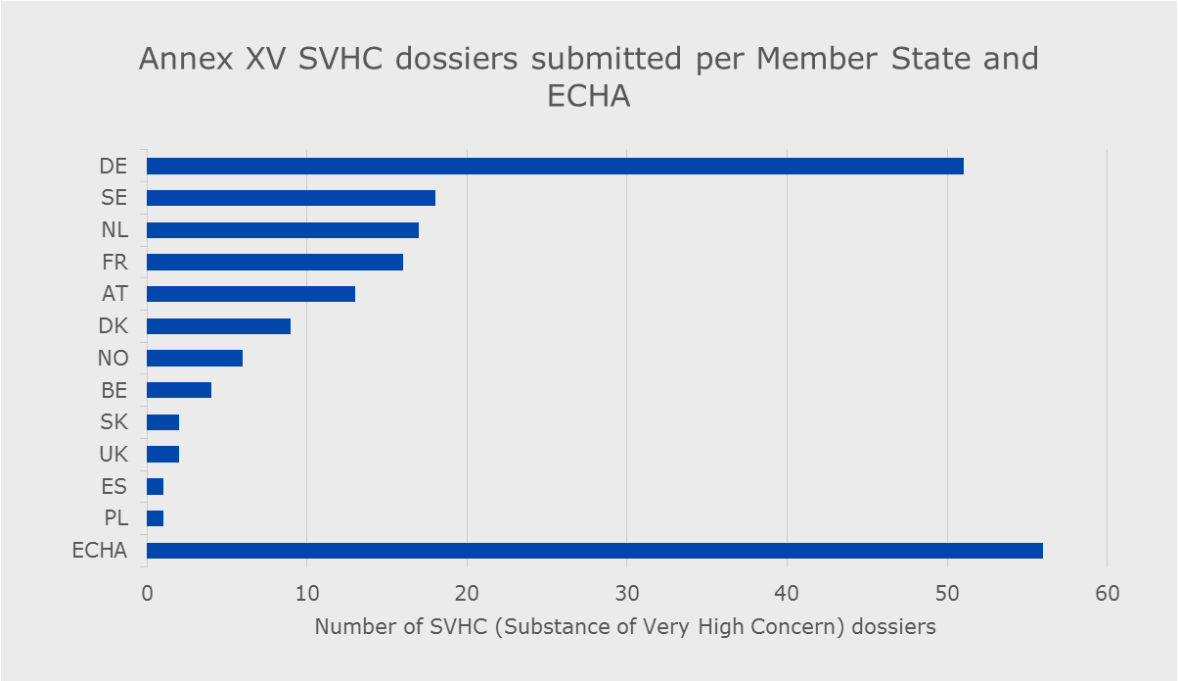


Figure 14: Number of Annex XV SVHC dossiers submitted per Member State and by ECHA.

[22] Note that each Candidate List entry has been counted only once i.e. the reasons (properties) for the identification have been counted separately (e.g. a substance being CMR and PBT/vPvB has been counted only under PBT/vPvB).

5.3.3 Recommendation for and inclusion on the Authorisation List

Substances identified as meeting the SVHC criteria are included on the Candidate List for eventual inclusion on the Authorisation List (Annex XIV to the REACH Regulation). ECHA prioritises substances from the Candidate List to control the order in which the substances should be included in Annex XIV. The substances with the highest priority are recommended first for inclusion. All those substances not recommended as well as newly added Candidate List substances are considered in future rounds.

According to Article 58(3), priority will normally be given to substances with PBT or vPvB properties, or wide dispersive use, or high volumes[23]. The prioritisation is made based mainly on information in the registration dossiers. However, information from public consultation on the SVHC identification and other REACH/CLP information is also considered.

The seventh recommendation[24] was sent to the Commission in November 2016. The eighth recommendation is under preparation and is expected to be sent to the Commission in the beginning of 2018.

Figure 15 gives an overview of the substances recommended by ECHA to be included in Annex XIV until the seventh recommendation as well as substances included on the Authorisation List (Annex XIV).

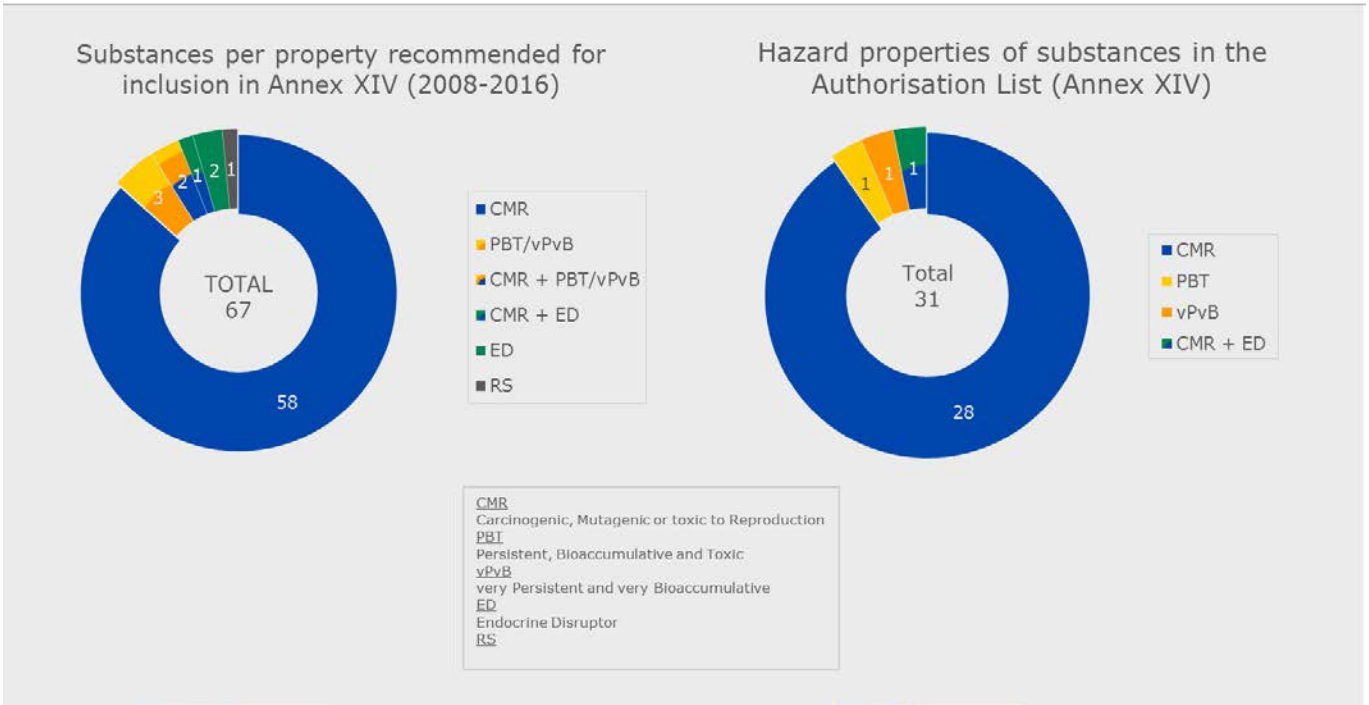


Figure 15: Overview of number and properties of substances recommended for inclusion in Annex XIV and included in Annex XIV (2008 – 2016)

[23] Prioritisation approach available at: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list

[24] The substances on the seventh recommendation are available at: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations

Table 8 gives an overview and names of the substances recommended by ECHA to be included in Annex XIV until the seventh recommendation. It also lists those substances which have been included in the Authorisation List (Annex XIV) and which not. The Commission has indicated in the preambles of each proposed amendment to Annex XIV the reasons for not taking forward the substances that were recommended by ECHA.

Table 8: Overview of substances recommended for inclusion in Annex XIV and substances included on Annex XIV (2008-2016)

Date of recommendation	Number of substances recommended	Amendment of Annex XIV	Number of substances included in Annex XIV	(Groups of) substances included in Annex XIV	(Groups of) substances not included in (draft) Annex XIV amendment
1st 1 June 2009	7	1st (17 Feb 2011)	6	Musk xylene, MDA, HBCDD, 3 phthalates	*[SCCP]*[25]
2nd 17 Dec 2010	8	2nd (14 Feb 2012)	8	1 phthalate, 2 arsenic substances, 3 lead chromate substances, TCEP, 2,4-DNT	
3rd 20 Dec 2011	13	3rd (17 Apr 2013)	8	Trichloroethylene, 7 chromium (VI) substances	5 Cobalt (II) compounds
4th 17 Jan 2013	10	4th (14 Aug 2014)	9	Polymeric/crude MDA, Diglyme, EDC, MOCA, 4 chromium (VI) substances	DMAC
5th 6 Feb 2014	5	*5th Draft amendment*	*1*	*4-tert-OPnEO*	DMF ADCA Al-RCF and Zr-RCF
6th 1 July 2015	15		*11*	*1-bromopropane,* *7 phthalates,* *anthracene oil,* *CTPHT,* *4-NPnEO*	4 boron substances
7th 10 Nov 2016	9	*[n.a.]*	*[n.a.]*	*[n.a.]*	
Total	***67***		**31 +** *12*	**31 +***12*	***15***

[25] SCCP was recommended but not included as the substance was included in the POP Regulation

5.3.4 Applications for authorisation and decisions on authorisation

Once a substance is included on the Authorisation List (Annex XIV), companies must not place it on the market or use it themselves after the sunset date unless an authorisation has been granted for a particular use.

Companies who want to continue to use the substance after the sunset date need to submit their applications for authorisation to ECHA.

The opinions of ECHA's committees contribute to the decision-making process of the European Commission which decides whether or not to grant an authorisation for the uses applied for.

Table 9 gives the number of applications for authorisations received from January 2013 until the end of December 2016 as well as the number of RAC/SEAC opinions and Commission's decisions.

Table 9: Number of applications for authorisation received from January 2013 – December 2016

Substance	Intrinsic properties in Annex XIV	Received applications	Applicants	Uses	RAC/SEAC opinions per use	Commission decisions per use
DEHP and DBP	CMR	8*	10	17	17	10
Lead chromate pigments (yellow and red)	CMR	1	1	12	12	12
HBCDD	PBT	1	13	2	2	2
Diarsenic trioxide	CMR	4	4	5	5	5
Trichloroethylene	CMR	13	15	19	19	5
Lead chromate	CMR	1	1	1	1	-
Chromium trioxide	CMR	25	61	41	21	-
Sodium dichromate	CMR	17	23	23	15	-
Sodium chromate	CMR	2	4	3	1	-
1,2-Dichloroethane (EDC)	CMR	15	17	19	5	-

Chromium trioxide, Sodium dichromate and Potassium dichromate	CMR	1	6	3	3	-
Potassium dichromate	CMR	4	4	7	4	-
Ammonium dichromate	CMR	3	5	4	2	-
Dichromium tris(chromate)	CMR	1	2	2	2	-
Chromium trioxide; Dichromium tris(chromate)	CMR	1	2	4	4	-
Strontium chromate	CMR	1	10	2	2	-
Potassium hydroxyoctaoxodizincatedichromate	CMR	1	5	2	2	-
bis(2-methoxyethyl) ether Diglyme	CMR	8	8	9	1	-
Arsenic acid	CMR	1	1	1	-	-
Chromic acid	CMR	1	1	1	1	-
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	CMR	1	1	2	-	-
2,2-dichloro-4,4'-methylenedianiline (MOCA)	CMR	1	1	1	-	-
Total		**111**	**195**	**180**	**119**	**34**

Annex 1: Progress monitoring indicators

Note that all progress monitoring indicators for the SVHC Roadmap are calculated starting with the implementation of the roadmap in 2013.

Table 10: Progress monitoring indicators target and results[26]

Indicators	Target	Result
Substance Screening 1: Percentage of substances identified for further work to clarify a concern (substance evaluation, CCH or proposed RRM (RMOA, CLH, other action)	- [27]	69.6%
Substance Screening 2: Percentage of substances for which the outcome of manual screening has been substance evaluation and which ends up later in an RMOA.	high	0
Assessment 1: Percentage of substances for further assessment (PBT/ED) or with need for advice which ends up in an RMOA/substance evaluation.	high	-
RMOA1: Number of (groups of) substances subject to an RMOA	55	16[28]
RMOA2: Extent to which (percentage of) RMOA conclusions resulted in regulatory follow-up	high	84.8%

With regard to substance screening around 70 % of 182 substances that were picked up by the IT based mass-screening were found to require further follow-up actions. This number is slightly lower than last year but as already indicated in the 2015 report this is linked to the fact that the same database is being searched for some years now with very similar scenarios (e.g. for CMR substances). In addition for several substances it was not possible to conclude the manual screening as work to clarify the hazardous properties is already ongoing under one of the REACH/CLP substances on a very similar substance. This clearly highlights the need to start working on groups of structurally similar substances rather than on single ones. In total, 22 Member States and EEA countries participated in the manual screening in 2016 which confirms the high interest from Member States in this activity.

It is still early to draw any conclusions on trends and effectiveness regarding substance evaluation as for most of the substances the process has not been completed, due to requests for further information. Between 2012 and 2016, 182 substances were evaluated and 49 (27%) evaluations concluded. Most of these conclusions were for substances for which no further information was requested. For 20 concluded cases, the evaluating Member State considered that further regulatory risk management may be needed. It is also still too early to draw conclusion on substances under assessment by the two expert groups as explained in the main report.

The extent to which the risk management options analysis (RMOA) conclusions received follow-up has however increased (84.8%); SVHC Identification and Restriction proposals were followed-up in respectively 87% and 100% of the cases compared to the expected number of regulatory

[26] All progress monitoring indicators for the SVHC Roadmap are calculated starting with the implementation of the roadmap in 2013.
[27] The target is to have substance screening one indicator high and at least equal to the baseline which is set as 2014.
[28] 16 new intentions but this covers 4 groups of substances and therefore cover many more than 16 substances.

proposals. Two CLH proposals have also been followed up which is a positive increase compared to last year. The trend that now most RMOA conclusions receive follow-up clearly reflects that it simply takes time for Member States to turn a conclusion into actual follow-up action.

Only 16 new intentions for RMOA were submitted however this covers 4 groups of substances and therefore cover many more than 16 substances. In addition it should be highlighted that a lot of work is done in clarifying concern of substances already at the level of screening which may conclude in no need for further action at present for the substances.

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